# Registration Decision Record

**Project:** sample_catalogue.csv
**Project ID:** proj-1
**Legislation:** MDR (12 devices)
**Devices:** 12
**Generated:** 2026-10-27 18:43:16 UTC
**Generated by:** ra.manager@beispiel-medizintechnik.de
**Record format version:** 2.0

All times in this record are UTC. The record has three parts, this statement, one decision card per device and the evidence appendix. The appendix holds every detail the first two parts summarise.

## Summary

- This record covers 12 devices. The last export was on 2026-10-08 21:40:12 UTC. Of the devices, 11 passed and 1 did not pass.
- 2 devices were removed from the project before this record was made. The evidence appendix names each one under "Devices removed".
- Rule errors remained at export on 1 device.
- 2 warnings were recorded at export.
- 1 EMDN code has a confidence below 60%.
- 1 value was left empty by a reviewer.
- 1 device has values with no recorded reviewer approval.
- The evidence appendix lists each one under "Exceptions recorded at export" and "State of the values at the time of this record".

## Files and audit trail

- The audit trail of 132 recorded events verifies against its stored hashes. Its head, the newest event when this record was made, is ca479fb283e914b9fd1c9f04c6cc2fbef4b8b0ba825b2571bfa15aee67ecaa8f.
- The hash can be checked at https://www.eudamate.eu/verify?hash=ca479fb283e914b9fd1c9f04c6cc2fbef4b8b0ba825b2571bfa15aee67ecaa8f
- A match shows that the hash is in an audit trail EUDAMate holds. It does not show that a given copy of this record was made from it. Compare the number of events and the time with this record.
- The file sample_catalogue.csv was uploaded on 2026-10-08 21:38:01 UTC. Its SHA-256 is 9f2c6a1e4b7d8053c1e9a2f6d4b8e0a7c3f5d1b9e6a2c8f4d0b7e3a9c5f1d6e2.
- The export on 2026-10-08 21:40:12 UTC produced a CSV with the SHA-256 4e8b1d7a3c9f2e6b0d5a8c1f7e3b9d2a6c4f0e8b5d1a7c3e9f2b6d0a4c8e1f5b.
- A SHA-256 computed over a file you hold matches a value here only if the file is byte for byte the one recorded.

## Approval

- Dr. Jana Becker, Head of Regulatory Affairs, was named as the person who approved the export on 2026-10-08 21:40:12 UTC. The exporting account confirmed this at that export. EUDAMate does not verify the name or the role.
- The audit trail holds only a fingerprint of this name and role in the event of this export, the SHA-256 84d8d94cce065e20dfd6dbe93d39082bac3562f0c04a22481aa55ec0be843030. Anyone can recompute it from the name, the role and the salt 3701e7f83f80eaeeec799f24f61fd6250d9c1eb6566ccceb645e0ac60b6eaa71 as the specification at https://www.eudamate.eu/rdr#approval-fingerprint describes.

# Decision cards

One card per device, in the order of the device list. Each line names the section of the evidence appendix that holds the detail.

### ART-1001, UDI-DI 04011616010013, "Zementfreier Hüftschaft Größe 1"

- **EMDN code.** P090804010201 (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH FIXED NECK, STRAIGHT). Source "AI suggestion", approved by ra.manager@beispiel-medizintechnik.de. Section 3.
- **Risk class.** Class III (CLASS_III), status "Approved". Section 3.5.
- **Legislation.** MDR, stated in the uploaded file. The header of the device section.
- **Values decided together.** 36 approved in a bulk review. Section 3.5 lists each value.
- **Items still open.** None recorded.
- **Result at export.** PASSED at export (2026-10-08 21:39:48 UTC). No rule errors, 0 warning(s), XSD check passed. Section 5.
- **Previous record.** No earlier record of this device is linked to it.

### ART-1002, UDI-DI 04011616010020, "Zementfreier Hüftschaft Größe 2"

- **EMDN code.** P090804010202 (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH FIXED NECK, ANATOMICAL). Source "AI suggestion", approved by ra.manager@beispiel-medizintechnik.de. Section 3.
- **Risk class.** Class IIb (CLASS_IIB), status "Changed by reviewer". Section 3.5.
- **Legislation.** MDR, stated in the uploaded file. The header of the device section.
- **Changed by a reviewer.** 1 value. Risk Class, reason "Expert judgment", by ra.manager@beispiel-medizintechnik.de. Section 4.
- **Values decided together.** 35 approved in a bulk review. Section 3.5 lists each value.
- **Items still open.** None recorded.
- **Result at export.** PASSED at export (2026-10-08 21:39:50 UTC). No rule errors, 0 warning(s), XSD check passed. Section 5.
- **Previous record.** No earlier record of this device is linked to it.

### ART-1003, UDI-DI 04011616010037, "Zementfreier Hüftschaft Größe 3"

- **EMDN code.** P090804010206 (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH MODULAR NECK, STRAIGHT). Source "AI suggestion", approved by ra.manager@beispiel-medizintechnik.de. Section 3.
- **Risk class.** Class III (CLASS_III), status "Approved". Section 3.5.
- **Legislation.** MDR, stated in the uploaded file. The header of the device section.
- **Values decided together.** 36 approved in a bulk review. Section 3.5 lists each value.
- **Items still open.** The EMDN code has a confidence below 60%. Section 3 and section 3.5.
- **Result at export.** PASSED at export (2026-10-08 21:39:52 UTC). No rule errors, 0 warning(s), XSD check passed. Section 5.
- **Previous record.** No earlier record of this device is linked to it.

## ART-1004, UDI-DI 04011616010044, "Zementfreier Hüftschaft Größe 4"

- **EMDN code.** P090804010207 (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH MODULAR NECK, ANATOMICAL). Source "AI suggestion", approved by ra.manager@beispiel-medizintechnik.de. Section 3.
- **Risk class.** Class III (CLASS_III), status "Approved". Section 3.5.
- **Legislation.** MDR, stated in the uploaded file. The header of the device section.
- **Values decided together.** 35 approved in a bulk review. Section 3.5 lists each value.
- **Items still open.** 1 value was left empty by a reviewer. Section 3 and section 3.5.
- **Result at export.** PASSED at export (2026-10-08 21:39:54 UTC). No rule errors, 0 warning(s), XSD check passed. Section 5.
- **Previous record.** No earlier record of this device is linked to it.

## ART-1005, UDI-DI 04011616010051, "Zementfreier Hüftschaft Größe 5"

- **EMDN code.** P090804030201 (REVISION UNCEMENTED FEMORAL STEMS, WITH FIXED NECK). Source "AI suggestion", approved by ra.manager@beispiel-medizintechnik.de. Section 3.
- **Risk class.** Class III (CLASS_III), status "Approved". Section 3.5.
- **Legislation.** MDR, stated in the uploaded file. The header of the device section.
- **Values decided together.** 36 approved in a bulk review. Section 3.5 lists each value.
- **Items still open.** None recorded.
- **Result at export.** PASSED at export (2026-10-08 21:39:56 UTC). No rule errors, 1 warning(s), XSD check passed. Section 5.
- **Previous record.** No earlier record of this device is linked to it.

## ART-1006, UDI-DI 04011616010068, "Zementfreier Hüftschaft Größe 6"

- **EMDN code.** P090804010201 (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH FIXED NECK, STRAIGHT). Source "AI suggestion", approved by ra.manager@beispiel-medizintechnik.de. Section 3.
- **Risk class.** Class III (CLASS_III), status "Approved". Section 3.5.
- **Legislation.** MDR, stated in the uploaded file. The header of the device section.
- **Values decided together.** 35 approved in a bulk review. Section 3.5 lists each value.
- **Items still open.** 1 value has no recorded reviewer approval. Section 3 and section 3.5.
- **Result at export.** PASSED at export (2026-10-08 21:39:58 UTC). No rule errors, 0 warning(s), XSD check passed. Section 5.
- **Previous record.** No earlier record of this device is linked to it.

## ART-1007, UDI-DI 04011616010075, "Zementfreier Hüftschaft Größe 7"

- **EMDN code.** P090804010202 (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH FIXED NECK, ANATOMICAL). Source "AI suggestion", approved by ra.manager@beispiel-medizintechnik.de. Section 3.
- **Risk class.** Class III (CLASS_III), status "Approved". Section 3.5.
- **Legislation.** MDR, stated in the uploaded file. The header of the device section.
- **Values decided together.** 36 approved in a bulk review. Section 3.5 lists each value.
- **Items still open.** None recorded.

- **Result at export.** NOT PASSED at export (2026-10-08 21:40:00 UTC). 1 rule error(s) remain, 0 warning(s), XSD check passed. Rule errors remained on this device at export. ra.manager@beispiel-medizintechnik.de confirmed the export anyway. Section 5.
- **Previous record.** No earlier record of this device is linked to it.

## ART-1008, UDI-DI 04011616010082, "Zementfreier Hüftschaft Größe 8"

- **EMDN code.** P090804010206 (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH MODULAR NECK, STRAIGHT). Source "AI suggestion", approved by ra.manager@beispiel-medizintechnik.de. Section 3.
- **Risk class.** Class III (CLASS_III), status "Approved". Section 3.5.
- **Legislation.** MDR, stated in the uploaded file. The header of the device section.
- **Values decided together.** 36 approved in a bulk review. Section 3.5 lists each value.
- **Items still open.** None recorded.
- **Result at export.** PASSED at export (2026-10-08 21:40:02 UTC). No rule errors, 0 warning(s), XSD check passed. Section 5.
- **Previous record.** No earlier record of this device is linked to it.

## ART-1009, UDI-DI 04011616010099, "Zementfreier Hüftschaft Größe 9"

- **EMDN code.** P090804010207 (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH MODULAR NECK, ANATOMICAL). Source "AI suggestion", approved by ra.manager@beispiel-medizintechnik.de. Section 3.
- **Risk class.** Class III (CLASS_III), status "Approved". Section 3.5.
- **Legislation.** MDR, stated in the uploaded file. The header of the device section.
- **Values decided together.** 36 approved in a bulk review. Section 3.5 lists each value.
- **Items still open.** None recorded.
- **Result at export.** PASSED at export (2026-10-08 21:40:04 UTC). No rule errors, 0 warning(s), XSD check passed. Section 5.
- **Previous record.** No earlier record of this device is linked to it.

## ART-1010, UDI-DI 04011616010105, "Zementfreier Hüftschaft Größe 10"

- **EMDN code.** P090804030201 (REVISION UNCEMENTED FEMORAL STEMS, WITH FIXED NECK). Source "AI suggestion", approved by ra.manager@beispiel-medizintechnik.de. Section 3.
- **Risk class.** Class III (CLASS_III), status "Approved". Section 3.5.
- **Legislation.** MDR, stated in the uploaded file. The header of the device section.
- **Values decided together.** 36 approved in a bulk review. Section 3.5 lists each value.
- **Items still open.** None recorded.
- **Result at export.** PASSED at export (2026-10-08 21:40:06 UTC). No rule errors, 1 warning(s), XSD check passed. Section 5.
- **Previous record.** No earlier record of this device is linked to it.

## ART-1011, UDI-DI 04011616010112, "Zementfreier Hüftschaft Größe 11"

- **EMDN code.** P090804010201 (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH FIXED NECK, STRAIGHT). Source "AI suggestion", approved by ra.manager@beispiel-medizintechnik.de. Section 3.
- **Risk class.** Class III (CLASS_III), status "Approved". Section 3.5.
- **Legislation.** MDR, stated in the uploaded file. The header of the device section.
- **Values decided together.** 36 approved in a bulk review. Section 3.5 lists each value.
- **Items still open.** None recorded.
- **Result at export.** PASSED at export (2026-10-08 21:40:08 UTC). No rule errors, 0 warning(s), XSD check passed. Section 5.
- **Previous record.** No earlier record of this device is linked to it.

## ART-1012, UDI-DI 04011616010129, "Zementfreier Hüftschaft Größe 12"

- **EMDN code.** P090804010202 (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH FIXED NECK, ANATOMICAL). Source "AI suggestion", approved by ra.manager@beispiel-medizintechnik.de. Section 3.
- **Risk class.** Class III (CLASS_III), status "Approved". Section 3.5.
- **Legislation.** MDR, stated in the uploaded file. The header of the device section.
- **Values decided together.** 36 approved in a bulk review. Section 3.5 lists each value.
- **Items still open.** None recorded.
- **Result at export.** PASSED at export (2026-10-08 21:40:10 UTC). No rule errors, 0 warning(s), XSD check passed. Section 5.
- **Previous record.** No earlier record of this device is linked to it.

# Evidence appendix

## Exceptions recorded at export

Each line names the device and the section of its record that holds the detail. A category with no entry is not listed.

**Rule errors that remained at export** (1)

- ART-1007, UDI-DI 04011616010075, "Zementfreier Hüftschaft Größe 7". 1 rule error(s) remained at export (BR-CONSISTENCY FLD-UDID-64). ra.manager@beispiel-medizintechnik.de confirmed the export anyway. Detail is in section 5.

**Warnings recorded at export** (2)

- ART-1005, UDI-DI 04011616010051, "Zementfreier Hüftschaft Größe 5". Warning pre-export check, FLD-UDID-63. The rule check reported "Notified Body code "0434" is not in the NANDO registry of designated notified bodies. Confirm the notified body before submission.". Detail is in section 5.
- ART-1010, UDI-DI 04011616010105, "Zementfreier Hüftschaft Größe 10". Warning pre-export check, FLD-UDID-63. The rule check reported "Notified Body code "0434" is not in the NANDO registry of designated notified bodies. Confirm the notified body before submission.". Detail is in section 5.

## State of the values at the time of this record

The values below are described as they stood at 2026-10-27 18:43:16 UTC, when this record was made. The record can be made again after an export.

**EMDN codes with a confidence below 60%** (1)

- ART-1003, UDI-DI 04011616010037, "Zementfreier Hüftschaft Größe 3". EMDN code P090804010206 (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH MODULAR NECK, STRAIGHT) was approved by ra.manager@beispiel-medizintechnik.de. The AI confidence was 45%. Detail is in section 3.

**Values a reviewer left empty** (1)

- ART-1004, UDI-DI 04011616010044, "Zementfreier Hüftschaft Größe 4". ra.manager@beispiel-medizintechnik.de left Sterilisation method (FLD-UDID-165) empty. Detail is in section 3.5.

**Values with no recorded reviewer approval** (1)

- ART-1006, UDI-DI 04011616010068, "Zementfreier Hüftschaft Größe 6". 1 value has no recorded reviewer approval (Measuring Function (FLD-UDID-31)). Detail is in section 3.5.

## Devices in this record

Each device is named by its reference number, UDI-DI and name. Its section starts with the same three.

| Reference | UDI-DI | Name | Legislation | Result at export |
|---|---|---|---|---|
| ART-1001 | 04011616010013 | Zementfreier Hüftschaft Größe 1 | MDR | Passed |
| ART-1002 | 04011616010020 | Zementfreier Hüftschaft Größe 2 | MDR | Passed |
| ART-1003 | 04011616010037 | Zementfreier Hüftschaft Größe 3 | MDR | Passed |
| ART-1004 | 04011616010044 | Zementfreier Hüftschaft Größe 4 | MDR | Passed |
| ART-1005 | 04011616010051 | Zementfreier Hüftschaft Größe 5 | MDR | Passed |
| ART-1006 | 04011616010068 | Zementfreier Hüftschaft Größe 6 | MDR | Passed |
| ART-1007 | 04011616010075 | Zementfreier Hüftschaft Größe 7 | MDR | Not passed |
| ART-1008 | 04011616010082 | Zementfreier Hüftschaft Größe 8 | MDR | Passed |
| ART-1009 | 04011616010099 | Zementfreier Hüftschaft Größe 9 | MDR | Passed |
| ART-1010 | 04011616010105 | Zementfreier Hüftschaft Größe 10 | MDR | Passed |
| ART-1011 | 04011616010112 | Zementfreier Hüftschaft Größe 11 | MDR | Passed |
| ART-1012 | 04011616010129 | Zementfreier Hüftschaft Größe 12 | MDR | Passed |

## Change capture

- Since 2026-10-08 21:38:04 UTC the audit trail records each saved change to a device field's value, review state, method, reason and justification, with the time of each change. Each device's section 4.1 lists the changes recorded for it. Where the database could not record a change, the change was saved anyway and the application recorded it where it could. The trail does not show whether the capture was switched off for a time after it started. A change made while it was off appears only where the application recorded it.
- This project has events from before that time. A change made before it appears in this record only where an earlier entry exists, under Human Overrides or the review log recorded before change capture.

## Bulk reviews

- Bulk review B-07A2C765. ra.manager@beispiel-medizintechnik.de confirmed it at 2026-10-08 21:39:06 UTC (event #66). 12 devices with 480 fields were selected. It ended at 2026-10-08 21:39:19 UTC (event #79) with 432 fields approved on 12 devices. No device failed.

## Devices removed

- 2026-10-08 21:39:46 UTC. ra.manager@beispiel-medizintechnik.de removed the device ART-2001, UDI-DI 04011616020012, "Entferntes Gerät 1". Event #106.
- 2026-10-08 21:39:47 UTC. ra.manager@beispiel-medizintechnik.de removed the device ART-2002, UDI-DI 04011616020029, "Entferntes Gerät 2". Event #107.

## Audit trail check

- **Intact.** 132 recorded events checked. The application's database refuses changes to audit events and deletes them only when the project's data is deleted under the retention policy. The stored hashes link

each event to the one before it. The check found no event that was altered or reordered since it was written, as far as the stored hashes show.

## Audit chain head

- Event hash ca479fb283e914b9fd1c9f04c6cc2fbef4b8b0ba825b2571bfa15aee67ecaa8f, the newest of 132 recorded events when this record was made.

## XSD schema check

- These are the results of the XSD format check at the last export (2026-10-08 21:40:10 UTC).
  - The XSD format check of this export's MDR data passed.

## How to read the EMDN classification

What the confidence printed with an EMDN code is depends on how the code was found, which the source beside it states. For a code the AI chose, it is the AI confidence, the AI's own rating after it checked the device's attributes. EUDAMate lowers that rating to at most a set limit where the code rests on the product name or on a hypothesis, where the description contradicts the code, where an attribute of the code is not in the description, where the AI's own description of the code, or its reasoning, does not match the code's EMDN term, where one code was shared by rows that differ, where a second model disagreed and where the code the AI proposed was not in EMDN, so one of its own listed alternatives was used. For a code taken from your earlier decision or from another row of the same upload with the same name, EUDAMate sets it at 85% for your earlier decision and 80% for the other row. For a code used by similar devices registered in EUDAMED, EUDAMate calculates it from those registrations. For a code found by a text match alone, EUDAMate sets the confidence from the text match, reduced by a set factor. The search match printed with each other listed code comes from the search that proposed it. Depending on the code it measures word overlap with the description, similarity in meaning to the description, the word overlap between product names, the share of similar EUDAMED registrations or the share of other customers' decisions. A code the AI proposed itself carries a search match only where the search had also found it. AI confidence is how sure the AI is about the code it chose. Search match is how strongly our search linked each alternative to your device. They measure different things, so a 58% search match does not mean the code is 58% likely to be right. A listed code can therefore have a higher search match than the chosen code.

## How this record relates to ISO 13485:2016

This record supports the manufacturer's QMS. It does not by itself demonstrate conformity with ISO 13485:2016 or any regulation.

| ISO 13485:2016 clause | How this record supports it |
|---|---|
| 4.2.5 Control of records | Supports your control of records. This record can be kept under your procedure for control of records. Identification, storage, protection, retention time and disposal stay under that procedure. |
| 4.2.3 Medical device file | Supports your medical device file. It can be referenced there as the record of how the EUDAMED registration data for these devices were prepared and reviewed. |

| ISO 13485:2016 clause | How this record supports it |
|---|---|
| 7.5.8 Identification | Supports the documentation of how UDI-related identifiers (Basic UDI-DI, UDI-DI, EUDAMED DI) and their registration data were derived from your source data and reviewed. |
| 4.1.6 Validation of software used in the QMS | Supports your validation of EUDAMate as software used in your QMS processes. Validation proportionate to risk is your responsibility. The validation results recorded here can be used as evidence in that validation. |

# Device ART-1001, UDI-DI 04011616010013, "Zementfreier Hüftschaft Größe 1"

**Reference number:** ART-1001
**Device UDI-DI:** 04011616010013
**Name:** Zementfreier Hüftschaft Größe 1
**Legislation:** MDR, stated in the uploaded file
**Reviewed by:** ra.manager@beispiel-medizintechnik.de on 2026-10-08 21:39:21 UTC
**Events in this record:** 13

## 1. Data Provenance

- **sample_catalogue.csv** (csv, 14 rows), uploaded 2026-10-08 21:38:01 UTC

## 2. Column Mapping

- Mapped: 38 of 40 columns (95%)
- By method: exact match 33, normalised name 1, alias 0, AI 4
- Mandatory fields with no source column at upload: Nomenclature code (EMDN)

## 3. EMDN Classification

- **Confirmed by reviewer, the AI suggestion:** P090804010201 (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH FIXED NECK, STRAIGHT), AI confidence 90%
  - AI reasoning: Description states 'zementfrei' (uncemented) and 'Hüftschaft' (hip stem), so the code is supported. Neck type is not stated. A second check by another model could not be completed, so the first answer is shown.
  - Other codes listed for comparison. Their search match is not the confidence printed above. P090804010202 (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH FIXED NECK, ANATOMICAL) (search match 19%); P090804010206 (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH MODULAR NECK, STRAIGHT) (search match 65%); P090804010207 (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH MODULAR NECK, ANATOMICAL) (search match 65%); P090804030201 (REVISION UNCEMENTED FEMORAL STEMS, WITH FIXED NECK) (search match 62%)

## 3.5 Field-Level Reasoning

Each value below shows the source column, rule, reviewer action or AI rationale that produced it.

| Field | Value | Status | Source | Confidence | Reasoning |
|---|---|---|---|---|---|
| Device Name (FLD-UDID-22) | Zementfreier Hüftschaft Größe 1 | Approved | Exact column match, approved in a bulk review | 100% | Column "Bezeichnung" matched "Device Name" exactly. |
| Applicable Legislation (FLD-UDID-11) | MDR | Approved | Exact column match, approved in a bulk review | 100% | Column "Rechtsgrundlage" matched "Applicable Legislation" exactly. |

| Field | Value | Status | Source | Confidence | Reasoning |
|---|---|---|---|---|---|
| Risk Class (FLD-UDID-16) | Class III (CLASS_III) | Approved | Exact column match, approved in a bulk review | 100% | Column "Risikoklasse" matched "Risk Class" exactly. |
| Legal Manufacturer SRN (FLD-UDID-10) | DE-MF-000000042 | Approved | Exact column match, approved in a bulk review | 100% | Column "Hersteller-SRN" matched "Legal Manufacturer SRN" exactly. |
| Implantable (FLD-UDID-30) | true | Approved | Exact column match, approved in a bulk review | 100% | Column "Implantierbar" matched "Implantable" exactly. |
| Active Device (FLD-UDID-28) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Aktives Medizinprodukt" matched "Active Device" exactly. |
| Measuring Function (FLD-UDID-31) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Messfunktion" matched "Measuring Function" exactly. |
| Reusable Surgical Instruments (FLD-UDID-32) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Wiederverwendbar" matched "Reusable Surgical Instruments" exactly. |
| Presence of animal tissues or cells (FLD-UDID-18) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Tierisches Gewebe" matched "Presence of animal tissues or cells" exactly. |
| Presence of human tissues or cells (FLD-UDID-23) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Menschliches Gewebe" matched "Presence of human tissues or cells" exactly. |
| Device intended to administer medicinal product (FLD-UDID-29) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Arzneimittelabgabe" matched "Device intended to administer medicinal product" exactly. |
| Substance - may be considered medicinal product (FLD-UDID-158) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Arzneimittel" matched "Substance - may be considered medicinal product" exactly. |
| Reference / Catalogue number (FLD-UDID-163) | ART-1001 | Approved | Exact column match, approved in a bulk review | 100% | Column "Artikelnummer" matched "Reference / Catalogue number" exactly. |
| Trade name (FLD-UDID-176) | DE: OrthoFlex Hip Stem Größe 1 | Approved | Exact column match, approved in a bulk review | 100% | Column "Handelsname" matched "Trade name" exactly. |
| UDI-DI code (FLD-UDID-178) | 04011616010013 | Approved | Exact column match, approved in a bulk review | 100% | Column "GTIN" matched "UDI-DI code" exactly. |
| Device labelled sterile (FLD-UDID-169) | true | Approved | Exact column match, approved in a bulk review | 100% | Column "Steril" matched "Device labelled sterile" exactly. |

| Field | Value | Status | Source | Confidence | Reasoning |
|---|---|---|---|---|---|
| Need for sterilisation before use (FLD-UDID-170) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Sterilisation" matched "Need for sterilisation before use" exactly. |
| Labelled as single use (FLD-UDID-167) | true | Approved | Exact column match, approved in a bulk review | 100% | Column "Einmalgebrauch" matched "Labelled as single use" exactly. |
| Reprocessed single use device (FLD-UDID-164) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Aufbereitet" matched "Reprocessed single use device" exactly. |
| Containing latex (FLD-UDID-156) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Enthält Latex" matched "Containing latex" exactly. |
| Device Status (FLD-UDID-130) | On the market (ON_THE_MARKET) | Approved | Exact column match, approved in a bulk review | 100% | Column "Marktstatus" matched "Device Status" exactly. |
| Type of UDI-PI (Production Identifier) (FLD-UDID-148) | Serialisation number (SERIALISATION_NUMBER) | Approved | Exact column match, approved in a bulk review | 100% | Column "UDI-PI Typ" matched "Type of UDI-PI (Production Identifier)" exactly. |
| Quantity of device (FLD-UDID-151) | 1 | Approved | Exact column match, approved in a bulk review | 100% | Column "Menge" matched "Quantity of device" exactly. |
| Certificate Type (FLD-UDID-60) | MDR type examination (MDR_TYPE_EXAMINATION) | Approved | Exact column match, approved in a bulk review | 100% | Column "Zertifikattyp" matched "Certificate Type" exactly. |
| Certificate Number (FLD-UDID-61) | 0123/2022/045678 | Approved | Exact column match, approved in a bulk review | 100% | Column "Zertifikatsnummer" matched "Certificate Number" exactly. |
| Notified Body (Certificate) (FLD-UDID-63) | 0123 | Approved | Exact column match, approved in a bulk review | 100% | Column "Benannte Stelle" matched "Notified Body (Certificate)" exactly. |
| Certificate Expiry Date (FLD-UDID-64) | 2027-04-30 | Approved | Exact column match, approved in a bulk review | 100% | Column "Ablaufdatum Zertifikat" matched "Certificate Expiry Date" exactly. |
| Member State where device is available (FLD-UDID-252) | DE,AT,FR,IT,ES,NL,BE,PL | Approved | Exact column match, approved in a bulk review | 100% | Column "Vertriebsland" matched "Member State where device is available" exactly. |
| Basic UDI-DI code (FLD-UDID-14) | 401161600010X5 | Approved | Column match after normalising the name, approved in a bulk review | 95% | Column "Basic-UDI-DI" matched "Basic UDI-DI code" after normalising punctuation/case. |
| Substance - human blood or plasma derived (FLD-UDID-155) | false | Approved | AI column mapping, approved in a bulk review | 95% | AI mapped column "Blut- oder Plasmaderivat" to "Substance - human blood or plasma derived" (confidence 0.95). German for human blood or plasma derived substance |

| Field | Value | Status | Source | Confidence | Reasoning |
|---|---|---|---|---|---|
| Market Info Start date (FLD-UDID-250) | 2023-06-15 | Approved | AI column mapping, approved in a bulk review | 90% | AI mapped column "Marktverfügbarkeit ab" to "Market Info Start date" (confidence 0.90). Complements mapped Member State availability |
| Issuing Entity Basic UDI-DI (FLD-UDID-01) | GS1 | Approved | Derived by rule, approved in a bulk review | 100% | Inferred from Basic UDI-DI code format, "401161600010X5" is a GS1 identifier. |
| Issuing Entity UDI-DI (FLD-UDID-291) | GS1 | Approved | Derived by rule, approved in a bulk review | 100% | Inferred from UDI-DI code format, "04011616010013" is a GS1 identifier. |
| System/Procedure Pack Type (FLD-UDID-12) | DEVICE | Approved | Declared by the customer, approved in a bulk review | 100% | Declared at project level by the project owner: every device in this project is a device in itself, not a system or a procedure pack (MDR Art. 22). EUDAMED field FLD-UDID-12. |
| Member State of first placing on EU market (FLD-UDID-137) | DE | Approved | Declared by the customer, approved in a bulk review | 100% | Declared at project level by the project owner: the devices in this project were first placed on the EU market in DE. EUDAMED field FLD-UDID-137. |
| Nomenclature code (EMDN) (FLD-UDID-149) | P090804010201 (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH FIXED NECK, STRAIGHT) | Approved | AI suggestion, approved by reviewer | 90% | Description states 'zementfrei' (uncemented) and 'Hüftschaft' (hip stem), so the code is supported. Neck type is not stated. A second check by another model could not be completed, so the first answer is shown. |
| Maximum number of reuses (FLD-UDID-157) | 0 | Approved | Derived by rule, approved by reviewer | 100% | Derived: device is labelled single use (FLD-UDID-167 = true), so maximum reuses is 0. |
| Sterilisation method (FLD-UDID-165) | ETO | Approved | Exact column match, approved in a bulk review | 100% | Column "Sterilisationsverfahren" matched "Sterilisation method" exactly. |

## 4. Human Overrides

No override by a reviewer was recorded. Section 4.1 lists every recorded change to this device, including approvals and other edits.

## 4.1 Change history

The device was imported at 2026-10-08 21:38:08 UTC with 38 fields (event #8). Each line is one recorded change, oldest first. The event number is its position in this project's audit trail.

**Nomenclature code (EMDN) (FLD-UDID-149)**

- 2026-10-08 21:38:10 UTC. The AI classifier, run by ra.manager@beispiel-medizintechnik.de, set a new suggestion. (empty) -> "P090804010201" (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH FIXED NECK, STRAIGHT). Event #10.
- 2026-10-08 21:39:20 UTC. ra.manager@beispiel-medizintechnik.de approved "P090804010201" (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH FIXED NECK, STRAIGHT). The AI had suggested "P090804010201" (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH FIXED NECK, STRAIGHT) with 90% confidence in event #9. Event #80.

**Maximum number of reuses (FLD-UDID-157)**

- 2026-10-08 21:38:10 UTC. The AI classifier, run by ra.manager@beispiel-medizintechnik.de, set a new suggestion. (empty) -> "0". Event #10.
- 2026-10-08 21:39:21 UTC. ra.manager@beispiel-medizintechnik.de approved "0". Event #81.

**Device Name (FLD-UDID-22)**

- 2026-10-08 21:39:07 UTC. ra.manager@beispiel-medizintechnik.de approved "Zementfreier Hüftschaft Größe 1" in bulk review B-07A2C765. Event #67.

**Applicable Legislation (FLD-UDID-11)**

- 2026-10-08 21:39:07 UTC. ra.manager@beispiel-medizintechnik.de approved "MDR" in bulk review B-07A2C765. Event #67.

**Risk Class (FLD-UDID-16)**

- 2026-10-08 21:39:07 UTC. ra.manager@beispiel-medizintechnik.de approved "CLASS_III" in bulk review B-07A2C765. Event #67.

**Legal Manufacturer SRN (FLD-UDID-10)**

- 2026-10-08 21:39:07 UTC. ra.manager@beispiel-medizintechnik.de approved "DE-MF-000000042" in bulk review B-07A2C765. Event #67.

**Implantable (FLD-UDID-30)**

- 2026-10-08 21:39:07 UTC. ra.manager@beispiel-medizintechnik.de approved "true" in bulk review B-07A2C765. Event #67.

**Active Device (FLD-UDID-28)**

- 2026-10-08 21:39:07 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #67.

**Measuring Function (FLD-UDID-31)**

- 2026-10-08 21:39:07 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #67.

**Reusable Surgical Instruments (FLD-UDID-32)**

- 2026-10-08 21:39:07 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #67.

**Presence of animal tissues or cells (FLD-UDID-18)**

- 2026-10-08 21:39:07 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #67.

**Presence of human tissues or cells (FLD-UDID-23)**

- 2026-10-08 21:39:07 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #67.

**Device intended to administer medicinal product (FLD-UDID-29)**

- 2026-10-08 21:39:07 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #67.

**Substance - may be considered medicinal product (FLD-UDID-158)**

- 2026-10-08 21:39:07 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #67.

**Reference / Catalogue number (FLD-UDID-163)**

- 2026-10-08 21:39:07 UTC. ra.manager@beispiel-medizintechnik.de approved "ART-1001" in bulk review B-07A2C765. Event #67.

**Trade name (FLD-UDID-176)**

- 2026-10-08 21:39:07 UTC. ra.manager@beispiel-medizintechnik.de approved "DE: OrthoFlex Hip Stem Größe 1" in bulk review B-07A2C765. Event #67.

**UDI-DI code (FLD-UDID-178)**

- 2026-10-08 21:39:07 UTC. ra.manager@beispiel-medizintechnik.de approved "04011616010013" in bulk review B-07A2C765. Event #67.

**Device labelled sterile (FLD-UDID-169)**

- 2026-10-08 21:39:07 UTC. ra.manager@beispiel-medizintechnik.de approved "true" in bulk review B-07A2C765. Event #67.

**Need for sterilisation before use (FLD-UDID-170)**

- 2026-10-08 21:39:07 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #67.

**Labelled as single use (FLD-UDID-167)**

- 2026-10-08 21:39:07 UTC. ra.manager@beispiel-medizintechnik.de approved "true" in bulk review B-07A2C765. Event #67.

**Reprocessed single use device (FLD-UDID-164)**

- 2026-10-08 21:39:07 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #67.

**Containing latex (FLD-UDID-156)**

- 2026-10-08 21:39:07 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #67.

**Device Status (FLD-UDID-130)**

- 2026-10-08 21:39:07 UTC. ra.manager@beispiel-medizintechnik.de approved "ON_THE_MARKET" in bulk review B-07A2C765. Event #67.

**Type of UDI-PI (Production Identifier) (FLD-UDID-148)**

- 2026-10-08 21:39:07 UTC. ra.manager@beispiel-medizintechnik.de approved "SERIALISATION_NUMBER" in bulk review B-07A2C765. Event #67.

**Quantity of device (FLD-UDID-151)**

- 2026-10-08 21:39:07 UTC. ra.manager@beispiel-medizintechnik.de approved "1" in bulk review B-07A2C765. Event #67.

**Certificate Type (FLD-UDID-60)**

- 2026-10-08 21:39:07 UTC. ra.manager@beispiel-medizintechnik.de approved "MDR_TYPE_EXAMINATION" in bulk review B-07A2C765. Event #67.

**Certificate Number (FLD-UDID-61)**

- 2026-10-08 21:39:07 UTC. ra.manager@beispiel-medizintechnik.de approved "0123/2022/045678" in bulk review B-07A2C765. Event #67.

**Notified Body (Certificate) (FLD-UDID-63)**

- 2026-10-08 21:39:07 UTC. ra.manager@beispiel-medizintechnik.de approved "0123" in bulk review B-07A2C765. Event #67.

**Certificate Expiry Date (FLD-UDID-64)**

- 2026-10-08 21:39:07 UTC. ra.manager@beispiel-medizintechnik.de approved "2027-04-30" in bulk review B-07A2C765. Event #67.

**Member State where device is available (FLD-UDID-252)**

- 2026-10-08 21:39:07 UTC. ra.manager@beispiel-medizintechnik.de approved "DE,AT,FR,IT,ES,NL,BE,PL" in bulk review B-07A2C765. Event #67.

**Basic UDI-DI code (FLD-UDID-14)**

- 2026-10-08 21:39:07 UTC. ra.manager@beispiel-medizintechnik.de approved "401161600010X5" in bulk review B-07A2C765. Event #67.

**Substance - human blood or plasma derived (FLD-UDID-155)**

- 2026-10-08 21:39:07 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #67.

**Market Info Start date (FLD-UDID-250)**

- 2026-10-08 21:39:07 UTC. ra.manager@beispiel-medizintechnik.de approved "2023-06-15" in bulk review B-07A2C765. Event #67.

**Issuing Entity Basic UDI-DI (FLD-UDID-01)**

- 2026-10-08 21:39:07 UTC. ra.manager@beispiel-medizintechnik.de approved "GS1" in bulk review B-07A2C765. Event #67.

**Issuing Entity UDI-DI (FLD-UDID-291)**

- 2026-10-08 21:39:07 UTC. ra.manager@beispiel-medizintechnik.de approved "GS1" in bulk review B-07A2C765. Event #67.

**System/Procedure Pack Type (FLD-UDID-12)**

- 2026-10-08 21:39:07 UTC. ra.manager@beispiel-medizintechnik.de approved "DEVICE" in bulk review B-07A2C765. Event #67.

**Member State of first placing on EU market (FLD-UDID-137)**

- 2026-10-08 21:39:07 UTC. ra.manager@beispiel-medizintechnik.de approved "DE" in bulk review B-07A2C765. Event #67.

**Sterilisation method (FLD-UDID-165)**

- 2026-10-08 21:39:07 UTC. ra.manager@beispiel-medizintechnik.de approved "ETO" in bulk review B-07A2C765. Event #67.

## 5. Validation History

- At upload, 2026-10-08 21:38:03 UTC. The rule check found 1 error(s) for this device
  - Error BR-MANDATORY, FLD-UDID-149. The rule check reported "Mandatory field missing for MDR".
- At export, 2026-10-08 21:39:48 UTC. 0 error(s), 0 warning(s) for this device under MDR
  - Language of a text. Trade name (FLD-UDID-176) is DE. The language code was written before the text in the uploaded file.
  - Passed EUDAMED's XSD format check.
- **Final status:** PASSED at export (2026-10-08 21:39:48 UTC). No rule errors, 0 warning(s), XSD check passed.

## 6. Milestones

- **Snapshot at upload** by ra.manager@beispiel-medizintechnik.de at 2026-10-08 21:38:07 UTC
- **Snapshot at export** by ra.manager@beispiel-medizintechnik.de at 2026-10-08 21:39:49 UTC

## 7. Full Timeline

- 2026-10-08 21:38:01 UTC. **File uploaded.** sample_catalogue.csv, 14 rows
- 2026-10-08 21:38:02 UTC. **Columns mapped.** 38 of 40 columns mapped (95%)
- 2026-10-08 21:38:03 UTC. **Validation at upload.** 1 error(s) for this device
- 2026-10-08 21:38:06 UTC. **Legislation determined.** MDR, stated in the uploaded file (FLD-UDID-11 as supplied (MDR))
- 2026-10-08 21:38:07 UTC. **Snapshot.** Snapshot at upload, by ra.manager@beispiel-medizintechnik.de
- 2026-10-08 21:38:08 UTC. **Device imported.** 38 fields imported, event #8

- 2026-10-08 21:38:09 UTC. **AI EMDN suggestion.** AI suggested P090804010201 (90% confidence)
- 2026-10-08 21:38:10 UTC. **Field change.** 2 field change(s) by the AI classifier, event #10
- 2026-10-08 21:39:07 UTC. **Field change.** 36 field change(s) by ra.manager@beispiel-medizintechnik.de, event #67
- 2026-10-08 21:39:20 UTC. **Field change.** 1 field change(s) by ra.manager@beispiel-medizintechnik.de, event #80
- 2026-10-08 21:39:21 UTC. **Field change.** 1 field change(s) by ra.manager@beispiel-medizintechnik.de, event #81
- 2026-10-08 21:39:48 UTC. **Validation at export.** 0 error(s), 0 warning(s). XSD check passed
- 2026-10-08 21:39:49 UTC. **Snapshot.** Snapshot at export, by ra.manager@beispiel-medizintechnik.de

# Device ART-1002, UDI-DI 04011616010020, "Zementfreier Hüftschaft Größe 2"

**Reference number:** ART-1002
**Device UDI-DI:** 04011616010020
**Name:** Zementfreier Hüftschaft Größe 2
**Legislation:** MDR, stated in the uploaded file
**Reviewed by:** ra.manager@beispiel-medizintechnik.de on 2026-10-08 21:39:24 UTC
**Events in this record:** 14

## 1. Data Provenance

- **sample_catalogue.csv** (csv, 14 rows), uploaded 2026-10-08 21:38:01 UTC

## 2. Column Mapping

- Mapped: 38 of 40 columns (95%)
- By method: exact match 33, normalised name 1, alias 0, AI 4
- Mandatory fields with no source column at upload: Nomenclature code (EMDN)

## 3. EMDN Classification

- **Confirmed by reviewer, the AI suggestion:** P090804010202 (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH FIXED NECK, ANATOMICAL), AI confidence 65%
  - AI reasoning: The description's own words did not point to P090804010202. Similar devices registered in EUDAMED use this code (5 manufacturers, 334 registrations, 22% of filings, registered name similar in meaning to "quill pdo quill pdo polydioxanone"). Same product family, USP 3-0. A second check by another model could not be completed, so the first answer is shown.
  - Other codes listed for comparison. Their search match is not the confidence printed above. P090804010201 (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH FIXED NECK, STRAIGHT) (search match 19%); P090804010206 (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH MODULAR NECK, STRAIGHT) (search match 65%); P090804010207 (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH MODULAR NECK, ANATOMICAL) (search match 65%); P090804030201 (REVISION UNCEMENTED FEMORAL STEMS, WITH FIXED NECK) (search match 62%)

## 3.5 Field-Level Reasoning

Each value below shows the source column, rule, reviewer action or AI rationale that produced it.

| Field | Value | Status | Source | Confidence | Reasoning |
|---|---|---|---|---|---|
| Device Name (FLD-UDID-22) | Zementfreier Hüftschaft Größe 2 | Approved | Exact column match, approved in a bulk review | 100% | Column "Bezeichnung" matched "Device Name" exactly. |
| Applicable Legislation (FLD-UDID-11) | MDR | Approved | Exact column match, approved in a bulk review | 100% | Column "Rechtsgrundlage" matched "Applicable Legislation" exactly. |
| Risk Class (FLD-UDID-16) | Class IIb (CLASS_IIB) | Changed by reviewer | Changed by reviewer, approved by reviewer | - | Changed by reviewer. Reason: Expert judgment. |
| Legal Manufacturer SRN (FLD-UDID-10) | DE-MF-000000042 | Approved | Exact column match, approved in a bulk review | 100% | Column "Hersteller-SRN" matched "Legal Manufacturer SRN" exactly. |
| Implantable (FLD-UDID-30) | true | Approved | Exact column match, approved in a bulk review | 100% | Column "Implantierbar" matched "Implantable" exactly. |
| Active Device (FLD-UDID-28) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Aktives Medizinprodukt" matched "Active Device" exactly. |
| Measuring Function (FLD-UDID-31) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Messfunktion" matched "Measuring Function" exactly. |
| Reusable Surgical Instruments (FLD-UDID-32) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Wiederverwendbar" matched "Reusable Surgical Instruments" exactly. |
| Presence of animal tissues or cells (FLD-UDID-18) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Tierisches Gewebe" matched "Presence of animal tissues or cells" exactly. |
| Presence of human tissues or cells (FLD-UDID-23) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Menschliches Gewebe" matched "Presence of human tissues or cells" exactly. |
| Device intended to administer medicinal product (FLD-UDID-29) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Arzneimittelabgabe" matched "Device intended to administer medicinal product" exactly. |
| Substance - may be considered medicinal product (FLD-UDID-158) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Arzneimittel" matched "Substance - may be considered medicinal product" exactly. |

| Field | Value | Status | Source | Confidence | Reasoning |
|---|---|---|---|---|---|
| Reference / Catalogue number (FLD-UDID-163) | ART-1002 | Approved | Exact column match, approved in a bulk review | 100% | Column "Artikelnummer" matched "Reference / Catalogue number" exactly. |
| Trade name (FLD-UDID-176) | DE: OrthoFlex Hip Stem Größe 2 | Approved | Exact column match, approved in a bulk review | 100% | Column "Handelsname" matched "Trade name" exactly. |
| UDI-DI code (FLD-UDID-178) | 04011616010020 | Approved | Exact column match, approved in a bulk review | 100% | Column "GTIN" matched "UDI-DI code" exactly. |
| Device labelled sterile (FLD-UDID-169) | true | Approved | Exact column match, approved in a bulk review | 100% | Column "Steril" matched "Device labelled sterile" exactly. |
| Need for sterilisation before use (FLD-UDID-170) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Sterilisation" matched "Need for sterilisation before use" exactly. |
| Labelled as single use (FLD-UDID-167) | true | Approved | Exact column match, approved in a bulk review | 100% | Column "Einmalgebrauch" matched "Labelled as single use" exactly. |
| Reprocessed single use device (FLD-UDID-164) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Aufbereitet" matched "Reprocessed single use device" exactly. |
| Containing latex (FLD-UDID-156) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Enthält Latex" matched "Containing latex" exactly. |
| Device Status (FLD-UDID-130) | On the market (ON_THE_MARKET) | Approved | Exact column match, approved in a bulk review | 100% | Column "Marktstatus" matched "Device Status" exactly. |
| Type of UDI-PI (Production Identifier) (FLD-UDID-148) | Serialisation number (SERIALISATION_NUMBER) | Approved | Exact column match, approved in a bulk review | 100% | Column "UDI-PI Typ" matched "Type of UDI-PI (Production Identifier)" exactly. |
| Quantity of device (FLD-UDID-151) | 1 | Approved | Exact column match, approved in a bulk review | 100% | Column "Menge" matched "Quantity of device" exactly. |
| Certificate Type (FLD-UDID-60) | MDR type examination (MDR_TYPE_EXAMINATION) | Approved | Exact column match, approved in a bulk review | 100% | Column "Zertifikattyp" matched "Certificate Type" exactly. |
| Certificate Number (FLD-UDID-61) | 0123/2022/045678 | Approved | Exact column match, approved in a bulk review | 100% | Column "Zertifikatsnummer" matched "Certificate Number" exactly. |
| Notified Body (Certificate) (FLD-UDID-63) | 0123 | Approved | Exact column match, approved in a bulk review | 100% | Column "Benannte Stelle" matched "Notified Body (Certificate)" exactly. |
| Certificate Expiry Date (FLD-UDID-64) | 2027-04-30 | Approved | Exact column match, approved in a bulk review | 100% | Column "Ablaufdatum Zertifikat" matched "Certificate Expiry Date" exactly. |

| Field | Value | Status | Source | Confidence | Reasoning |
|---|---|---|---|---|---|
| Member State where device is available (FLD-UDID-252) | DE,AT,FR,IT,ES,NL,BE,PL | Approved | Exact column match, approved in a bulk review | 100% | Column "Vertriebsland" matched "Member State where device is available" exactly. |
| Basic UDI-DI code (FLD-UDID-14) | 401161600010X5 | Approved | Column match after normalising the name, approved in a bulk review | 95% | Column "Basic-UDI-DI" matched "Basic UDI-DI code" after normalising punctuation/case. |
| Substance - human blood or plasma derived (FLD-UDID-155) | false | Approved | AI column mapping, approved in a bulk review | 95% | AI mapped column "Blut- oder Plasmaderivat" to "Substance - human blood or plasma derived" (confidence 0.95). German for human blood or plasma derived substance |
| Market Info Start date (FLD-UDID-250) | 2023-06-15 | Approved | AI column mapping, approved in a bulk review | 90% | AI mapped column "Marktverfügbarkeit ab" to "Market Info Start date" (confidence 0.90). Complements mapped Member State availability |
| Issuing Entity Basic UDI-DI (FLD-UDID-01) | GS1 | Approved | Derived by rule, approved in a bulk review | 100% | Inferred from Basic UDI-DI code format, "401161600010X5" is a GS1 identifier. |
| Issuing Entity UDI-DI (FLD-UDID-291) | GS1 | Approved | Derived by rule, approved in a bulk review | 100% | Inferred from UDI-DI code format, "04011616010020" is a GS1 identifier. |
| System/Procedure Pack Type (FLD-UDID-12) | DEVICE | Approved | Declared by the customer, approved in a bulk review | 100% | Declared at project level by the project owner: every device in this project is a device in itself, not a system or a procedure pack (MDR Art. 22). EUDAMED field FLD-UDID-12. |
| Member State of first placing on EU market (FLD-UDID-137) | DE | Approved | Declared by the customer, approved in a bulk review | 100% | Declared at project level by the project owner: the devices in this project were first placed on the EU market in DE. EUDAMED field FLD-UDID-137. |

| Field | Value | Status | Source | Confidence | Reasoning |
|---|---|---|---|---|---|
| Nomenclature code (EMDN) (FLD-UDID-149) | P090804010202 (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH FIXED NECK, ANATOMICAL) | Approved | AI suggestion, approved by reviewer | 65% | The description's own words did not point to P090804010202. Similar devices registered in EUDAMED use this code (5 manufacturers, 334 registrations, 22% of filings, registered name similar in meaning to "quill pdo quill pdo polydioxanone"). Same product family, USP 3-0. A second check by another model could not be completed, so the first answer is shown. |
| Maximum number of reuses (FLD-UDID-157) | 0 | Approved | Derived by rule, approved by reviewer | 100% | Derived: device is labelled single use (FLD-UDID-167 = true), so maximum reuses is 0. |
| Sterilisation method (FLD-UDID-165) | ETO | Approved | Exact column match, approved in a bulk review | 100% | Column "Sterilisationsverfahren" matched "Sterilisation method" exactly. |

## 4. Human Overrides

- **Risk Class** (FLD-UDID-16) changed from CLASS_III to CLASS_IIB
  - Reason: Expert judgment
  - Recorded by ra.manager@beispiel-medizintechnik.de at 2026-10-08 21:39:24 UTC (event #84, see 4.1)

## 4.1 Change history

The device was imported at 2026-10-08 21:38:13 UTC with 38 fields (event #13). Each line is one recorded change, oldest first. The event number is its position in this project's audit trail.

**Nomenclature code (EMDN) (FLD-UDID-149)**

- 2026-10-08 21:38:15 UTC. The AI classifier, run by ra.manager@beispiel-medizintechnik.de, set a new suggestion. (empty) -> "P090804010202" (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH FIXED NECK, ANATOMICAL). Event #15.
- 2026-10-08 21:39:22 UTC. ra.manager@beispiel-medizintechnik.de approved "P090804010202" (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH FIXED NECK, ANATOMICAL). The AI had suggested "P090804010202" (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH FIXED NECK, ANATOMICAL) with 65% confidence in event #14. Event #82.

**Maximum number of reuses (FLD-UDID-157)**

- 2026-10-08 21:38:15 UTC. The AI classifier, run by ra.manager@beispiel-medizintechnik.de, set a new suggestion. (empty) -> "0". Event #15.
- 2026-10-08 21:39:23 UTC. ra.manager@beispiel-medizintechnik.de approved "0". Event #83.

**Device Name (FLD-UDID-22)**

- 2026-10-08 21:39:08 UTC. ra.manager@beispiel-medizintechnik.de approved "Zementfreier Hüftschaft Größe 2" in bulk review B-07A2C765. Event #68.

**Applicable Legislation (FLD-UDID-11)**

- 2026-10-08 21:39:08 UTC. ra.manager@beispiel-medizintechnik.de approved "MDR" in bulk review B-07A2C765. Event #68.

**Legal Manufacturer SRN (FLD-UDID-10)**

- 2026-10-08 21:39:08 UTC. ra.manager@beispiel-medizintechnik.de approved "DE-MF-000000042" in bulk review B-07A2C765. Event #68.

**Implantable (FLD-UDID-30)**

- 2026-10-08 21:39:08 UTC. ra.manager@beispiel-medizintechnik.de approved "true" in bulk review B-07A2C765. Event #68.

**Active Device (FLD-UDID-28)**

- 2026-10-08 21:39:08 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #68.

**Measuring Function (FLD-UDID-31)**

- 2026-10-08 21:39:08 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #68.

**Reusable Surgical Instruments (FLD-UDID-32)**

- 2026-10-08 21:39:08 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #68.

**Presence of animal tissues or cells (FLD-UDID-18)**

- 2026-10-08 21:39:08 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #68.

**Presence of human tissues or cells (FLD-UDID-23)**

- 2026-10-08 21:39:08 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #68.

**Device intended to administer medicinal product (FLD-UDID-29)**

- 2026-10-08 21:39:08 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #68.

**Substance - may be considered medicinal product (FLD-UDID-158)**

- 2026-10-08 21:39:08 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #68.

**Reference / Catalogue number (FLD-UDID-163)**

- 2026-10-08 21:39:08 UTC. ra.manager@beispiel-medizintechnik.de approved "ART-1002" in bulk review B-07A2C765. Event #68.

**Trade name (FLD-UDID-176)**

- 2026-10-08 21:39:08 UTC. ra.manager@beispiel-medizintechnik.de approved "DE: OrthoFlex Hip Stem Größe 2" in bulk review B-07A2C765. Event #68.

**UDI-DI code (FLD-UDID-178)**

- 2026-10-08 21:39:08 UTC. ra.manager@beispiel-medizintechnik.de approved "04011616010020" in bulk review B-07A2C765. Event #68.

**Device labelled sterile (FLD-UDID-169)**

- 2026-10-08 21:39:08 UTC. ra.manager@beispiel-medizintechnik.de approved "true" in bulk review B-07A2C765. Event #68.

**Need for sterilisation before use (FLD-UDID-170)**

- 2026-10-08 21:39:08 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #68.

**Labelled as single use (FLD-UDID-167)**

- 2026-10-08 21:39:08 UTC. ra.manager@beispiel-medizintechnik.de approved "true" in bulk review B-07A2C765. Event #68.

**Reprocessed single use device (FLD-UDID-164)**

- 2026-10-08 21:39:08 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #68.

**Containing latex (FLD-UDID-156)**

- 2026-10-08 21:39:08 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #68.

**Device Status (FLD-UDID-130)**

- 2026-10-08 21:39:08 UTC. ra.manager@beispiel-medizintechnik.de approved "ON_THE_MARKET" in bulk review B-07A2C765. Event #68.

**Type of UDI-PI (Production Identifier) (FLD-UDID-148)**

- 2026-10-08 21:39:08 UTC. ra.manager@beispiel-medizintechnik.de approved "SERIALISATION_NUMBER" in bulk review B-07A2C765. Event #68.

**Quantity of device (FLD-UDID-151)**

- 2026-10-08 21:39:08 UTC. ra.manager@beispiel-medizintechnik.de approved "1" in bulk review B-07A2C765. Event #68.

**Certificate Type (FLD-UDID-60)**

- 2026-10-08 21:39:08 UTC. ra.manager@beispiel-medizintechnik.de approved "MDR_TYPE_EXAMINATION" in bulk review B-07A2C765. Event #68.

**Certificate Number (FLD-UDID-61)**

- 2026-10-08 21:39:08 UTC. ra.manager@beispiel-medizintechnik.de approved "0123/2022/045678" in bulk review B-07A2C765. Event #68.

**Notified Body (Certificate) (FLD-UDID-63)**

- 2026-10-08 21:39:08 UTC. ra.manager@beispiel-medizintechnik.de approved "0123" in bulk review B-07A2C765. Event #68.

**Certificate Expiry Date (FLD-UDID-64)**

- 2026-10-08 21:39:08 UTC. ra.manager@beispiel-medizintechnik.de approved "2027-04-30" in bulk review B-07A2C765. Event #68.

**Member State where device is available (FLD-UDID-252)**

- 2026-10-08 21:39:08 UTC. ra.manager@beispiel-medizintechnik.de approved "DE,AT,FR,IT,ES,NL,BE,PL" in bulk review B-07A2C765. Event #68.

**Basic UDI-DI code (FLD-UDID-14)**

- 2026-10-08 21:39:08 UTC. ra.manager@beispiel-medizintechnik.de approved "401161600010X5" in bulk review B-07A2C765. Event #68.

**Substance - human blood or plasma derived (FLD-UDID-155)**

- 2026-10-08 21:39:08 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #68.

**Market Info Start date (FLD-UDID-250)**

- 2026-10-08 21:39:08 UTC. ra.manager@beispiel-medizintechnik.de approved "2023-06-15" in bulk review B-07A2C765. Event #68.

**Issuing Entity Basic UDI-DI (FLD-UDID-01)**

- 2026-10-08 21:39:08 UTC. ra.manager@beispiel-medizintechnik.de approved "GS1" in bulk review B-07A2C765. Event #68.

**Issuing Entity UDI-DI (FLD-UDID-291)**

- 2026-10-08 21:39:08 UTC. ra.manager@beispiel-medizintechnik.de approved "GS1" in bulk review B-07A2C765. Event #68.

**System/Procedure Pack Type (FLD-UDID-12)**

- 2026-10-08 21:39:08 UTC. ra.manager@beispiel-medizintechnik.de approved "DEVICE" in bulk review B-07A2C765. Event #68.

**Member State of first placing on EU market (FLD-UDID-137)**

- 2026-10-08 21:39:08 UTC. ra.manager@beispiel-medizintechnik.de approved "DE" in bulk review B-07A2C765. Event #68.

**Sterilisation method (FLD-UDID-165)**

- 2026-10-08 21:39:08 UTC. ra.manager@beispiel-medizintechnik.de approved "ETO" in bulk review B-07A2C765. Event #68.

**Risk Class (FLD-UDID-16)**

- 2026-10-08 21:39:24 UTC. ra.manager@beispiel-medizintechnik.de changed the value. "CLASS_III" -> "CLASS_IIB". Reason Expert judgment. Justification "Rule 8 applies to this stem". Event #84.

## 5. Validation History

- At upload, 2026-10-08 21:38:03 UTC. The rule check found 1 error(s) for this device
  - Error BR-MANDATORY, FLD-UDID-149. The rule check reported "Mandatory field missing for MDR".
- At export, 2026-10-08 21:39:50 UTC. 0 error(s), 0 warning(s) for this device under MDR
  - Language of a text. Trade name (FLD-UDID-176) is DE. The language code was written before the text in the uploaded file.
  - Passed EUDAMED's XSD format check.
- **Final status:** PASSED at export (2026-10-08 21:39:50 UTC). No rule errors, 0 warning(s), XSD check passed.

## 6. Milestones

- **Snapshot at upload** by ra.manager@beispiel-medizintechnik.de at 2026-10-08 21:38:12 UTC
- **Snapshot at export** by ra.manager@beispiel-medizintechnik.de at 2026-10-08 21:39:51 UTC

## 7. Full Timeline

- 2026-10-08 21:38:01 UTC. **File uploaded.** sample_catalogue.csv, 14 rows
- 2026-10-08 21:38:02 UTC. **Columns mapped.** 38 of 40 columns mapped (95%)
- 2026-10-08 21:38:03 UTC. **Validation at upload.** 1 error(s) for this device
- 2026-10-08 21:38:11 UTC. **Legislation determined.** MDR, stated in the uploaded file (FLD-UDID-11 as supplied (MDR))
- 2026-10-08 21:38:12 UTC. **Snapshot.** Snapshot at upload, by ra.manager@beispiel-medizintechnik.de
- 2026-10-08 21:38:13 UTC. **Device imported.** 38 fields imported, event #13
- 2026-10-08 21:38:14 UTC. **AI EMDN suggestion.** AI suggested P090804010202 (65% confidence)
- 2026-10-08 21:38:15 UTC. **Field change.** 2 field change(s) by the AI classifier, event #15
- 2026-10-08 21:39:08 UTC. **Field change.** 35 field change(s) by ra.manager@beispiel-medizintechnik.de, event #68
- 2026-10-08 21:39:22 UTC. **Field change.** 1 field change(s) by ra.manager@beispiel-medizintechnik.de, event #82
- 2026-10-08 21:39:23 UTC. **Field change.** 1 field change(s) by ra.manager@beispiel-medizintechnik.de, event #83
- 2026-10-08 21:39:24 UTC. **Field change.** 1 field change(s) by ra.manager@beispiel-medizintechnik.de, event #84
- 2026-10-08 21:39:50 UTC. **Validation at export.** 0 error(s), 0 warning(s). XSD check passed
- 2026-10-08 21:39:51 UTC. **Snapshot.** Snapshot at export, by ra.manager@beispiel-medizintechnik.de

# Device ART-1003, UDI-DI 04011616010037, "Zementfreier Hüftschaft Größe 3"

**Reference number:** ART-1003
**Device UDI-DI:** 04011616010037
**Name:** Zementfreier Hüftschaft Größe 3
**Legislation:** MDR, stated in the uploaded file
**Reviewed by:** ra.manager@beispiel-medizintechnik.de on 2026-10-08 21:39:26 UTC
**Events in this record:** 13

## 1. Data Provenance

- **sample_catalogue.csv** (csv, 14 rows), uploaded 2026-10-08 21:38:01 UTC

## 2. Column Mapping

- Mapped: 38 of 40 columns (95%)
- By method: exact match 33, normalised name 1, alias 0, AI 4
- Mandatory fields with no source column at upload: Nomenclature code (EMDN)

## 3. EMDN Classification

- **Confirmed by reviewer, the AI suggestion:** P090804010206 (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH MODULAR NECK, STRAIGHT), AI confidence 45%
  - AI reasoning: Description states 'zementfrei' (uncemented) and 'Hüftschaft' (hip stem), so the code is supported. Neck type is not stated. A second check by another model could not be completed, so the first answer is shown.
  - Other codes listed for comparison. Their search match is not the confidence printed above. P090804010201 (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH FIXED NECK, STRAIGHT) (search match 19%); P090804010202 (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH FIXED NECK, ANATOMICAL) (search match 65%); P090804010207 (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH MODULAR NECK, ANATOMICAL) (search match 65%); P090804030201 (REVISION UNCEMENTED FEMORAL STEMS, WITH FIXED NECK) (search match 62%)
  - A listed code has a higher search match than the chosen code. The two numbers measure different things.

## 3.5 Field-Level Reasoning

Each value below shows the source column, rule, reviewer action or AI rationale that produced it.

| Field | Value | Status | Source | Confidence | Reasoning |
|---|---|---|---|---|---|
| Device Name (FLD-UDID-22) | Zementfreier Hüftschaft Größe 3 | Approved | Exact column match, approved in a bulk review | 100% | Column "Bezeichnung" matched "Device Name" exactly. |
| Applicable Legislation (FLD-UDID-11) | MDR | Approved | Exact column match, approved in a bulk review | 100% | Column "Rechtsgrundlage" matched "Applicable Legislation" exactly. |
| Risk Class (FLD-UDID-16) | Class III (CLASS_III) | Approved | Exact column match, approved in a bulk review | 100% | Column "Risikoklasse" matched "Risk Class" exactly. |
| Legal Manufacturer SRN (FLD-UDID-10) | DE-MF-000000042 | Approved | Exact column match, approved in a bulk review | 100% | Column "Hersteller-SRN" matched "Legal Manufacturer SRN" exactly. |
| Implantable (FLD-UDID-30) | true | Approved | Exact column match, approved in a bulk review | 100% | Column "Implantierbar" matched "Implantable" exactly. |
| Active Device (FLD-UDID-28) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Aktives Medizinprodukt" matched "Active Device" exactly. |
| Measuring Function (FLD-UDID-31) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Messfunktion" matched "Measuring Function" exactly. |
| Reusable Surgical Instruments (FLD-UDID-32) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Wiederverwendbar" matched "Reusable Surgical Instruments" exactly. |
| Presence of animal tissues or cells (FLD-UDID-18) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Tierisches Gewebe" matched "Presence of animal tissues or cells" exactly. |
| Presence of human tissues or cells (FLD-UDID-23) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Menschliches Gewebe" matched "Presence of human tissues or cells" exactly. |
| Device intended to administer medicinal product (FLD-UDID-29) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Arzneimittelabgabe" matched "Device intended to administer medicinal product" exactly. |
| Substance - may be considered medicinal product (FLD-UDID-158) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Arzneimittel" matched "Substance - may be considered medicinal product" exactly. |
| Reference / Catalogue number (FLD-UDID-163) | ART-1003 | Approved | Exact column match, approved in a bulk review | 100% | Column "Artikelnummer" matched "Reference / Catalogue number" exactly. |

| Field | Value | Status | Source | Confidence | Reasoning |
|---|---|---|---|---|---|
| Trade name (FLD-UDID-176) | DE: OrthoFlex Hip Stem Größe 3 | Approved | Exact column match, approved in a bulk review | 100% | Column "Handelsname" matched "Trade name" exactly. |
| UDI-DI code (FLD-UDID-178) | 04011616010037 | Approved | Exact column match, approved in a bulk review | 100% | Column "GTIN" matched "UDI-DI code" exactly. |
| Device labelled sterile (FLD-UDID-169) | true | Approved | Exact column match, approved in a bulk review | 100% | Column "Steril" matched "Device labelled sterile" exactly. |
| Need for sterilisation before use (FLD-UDID-170) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Sterilisation" matched "Need for sterilisation before use" exactly. |
| Labelled as single use (FLD-UDID-167) | true | Approved | Exact column match, approved in a bulk review | 100% | Column "Einmalgebrauch" matched "Labelled as single use" exactly. |
| Reprocessed single use device (FLD-UDID-164) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Aufbereitet" matched "Reprocessed single use device" exactly. |
| Containing latex (FLD-UDID-156) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Enthält Latex" matched "Containing latex" exactly. |
| Device Status (FLD-UDID-130) | On the market (ON_THE_MARKET) | Approved | Exact column match, approved in a bulk review | 100% | Column "Marktstatus" matched "Device Status" exactly. |
| Type of UDI-PI (Production Identifier) (FLD-UDID-148) | Serialisation number (SERIALISATION_NUMBER) | Approved | Exact column match, approved in a bulk review | 100% | Column "UDI-PI Typ" matched "Type of UDI-PI (Production Identifier)" exactly. |
| Quantity of device (FLD-UDID-151) | 1 | Approved | Exact column match, approved in a bulk review | 100% | Column "Menge" matched "Quantity of device" exactly. |
| Certificate Type (FLD-UDID-60) | MDR type examination (MDR_TYPE_EXAMINATION) | Approved | Exact column match, approved in a bulk review | 100% | Column "Zertifikattyp" matched "Certificate Type" exactly. |
| Certificate Number (FLD-UDID-61) | 0123/2022/045678 | Approved | Exact column match, approved in a bulk review | 100% | Column "Zertifikatsnummer" matched "Certificate Number" exactly. |
| Notified Body (Certificate) (FLD-UDID-63) | 0123 | Approved | Exact column match, approved in a bulk review | 100% | Column "Benannte Stelle" matched "Notified Body (Certificate)" exactly. |
| Certificate Expiry Date (FLD-UDID-64) | 2027-04-30 | Approved | Exact column match, approved in a bulk review | 100% | Column "Ablaufdatum Zertifikat" matched "Certificate Expiry Date" exactly. |
| Member State where device is available (FLD-UDID-252) | DE,AT,FR,IT,ES,NL,BE,PL | Approved | Exact column match, approved in a bulk review | 100% | Column "Vertriebsland" matched "Member State where device is available" exactly. |
| Basic UDI-DI code (FLD-UDID-14) | 401161600010X5 | Approved | Column match after normalising the name, approved in a bulk review | 95% | Column "Basic-UDI-DI" matched "Basic UDI-DI code" after normalising punctuation/case. |

| Field | Value | Status | Source | Confidence | Reasoning |
|---|---|---|---|---|---|
| Substance - human blood or plasma derived (FLD-UDID-155) | false | Approved | AI column mapping, approved in a bulk review | 95% | AI mapped column "Blut- oder Plasmaderivat" to "Substance - human blood or plasma derived" (confidence 0.95). German for human blood or plasma derived substance |
| Market Info Start date (FLD-UDID-250) | 2023-06-15 | Approved | AI column mapping, approved in a bulk review | 90% | AI mapped column "Marktverfügbarkeit ab" to "Market Info Start date" (confidence 0.90). Complements mapped Member State availability |
| Issuing Entity Basic UDI-DI (FLD-UDID-01) | GS1 | Approved | Derived by rule, approved in a bulk review | 100% | Inferred from Basic UDI-DI code format, "401161600010X5" is a GS1 identifier. |
| Issuing Entity UDI-DI (FLD-UDID-291) | GS1 | Approved | Derived by rule, approved in a bulk review | 100% | Inferred from UDI-DI code format, "04011616010037" is a GS1 identifier. |
| System/Procedure Pack Type (FLD-UDID-12) | DEVICE | Approved | Declared by the customer, approved in a bulk review | 100% | Declared at project level by the project owner: every device in this project is a device in itself, not a system or a procedure pack (MDR Art. 22). EUDAMED field FLD-UDID-12. |
| Member State of first placing on EU market (FLD-UDID-137) | DE | Approved | Declared by the customer, approved in a bulk review | 100% | Declared at project level by the project owner: the devices in this project were first placed on the EU market in DE. EUDAMED field FLD-UDID-137. |
| Nomenclature code (EMDN) (FLD-UDID-149) | P090804010206 (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH MODULAR NECK, STRAIGHT) | Approved | AI suggestion, approved by reviewer | 45% | Description states 'zementfrei' (uncemented) and 'Hüftschaft' (hip stem), so the code is supported. Neck type is not stated. A second check by another model could not be completed, so the first answer is shown. |
| Maximum number of reuses (FLD-UDID-157) | 0 | Approved | Derived by rule, approved by reviewer | 100% | Derived: device is labelled single use (FLD-UDID-167 = true), so maximum reuses is 0. |
| Sterilisation method (FLD-UDID-165) | ETO | Approved | Exact column match, approved in a bulk review | 100% | Column "Sterilisationsverfahren" matched "Sterilisation method" exactly. |

## 4. Human Overrides

No override by a reviewer was recorded. Section 4.1 lists every recorded change to this device, including approvals and other edits.

## 4.1 Change history

The device was imported at 2026-10-08 21:38:18 UTC with 38 fields (event #18). Each line is one recorded change, oldest first. The event number is its position in this project's audit trail.

**Nomenclature code (EMDN) (FLD-UDID-149)**

- 2026-10-08 21:38:20 UTC. The AI classifier, run by ra.manager@beispiel-medizintechnik.de, set a new suggestion. (empty) -> "P090804010206" (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH MODULAR NECK, STRAIGHT). Event #20.
- 2026-10-08 21:39:25 UTC. ra.manager@beispiel-medizintechnik.de approved "P090804010206" (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH MODULAR NECK, STRAIGHT). The AI had suggested "P090804010206" (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH MODULAR NECK, STRAIGHT) with 45% confidence in event #19. Event #85.

**Maximum number of reuses (FLD-UDID-157)**

- 2026-10-08 21:38:20 UTC. The AI classifier, run by ra.manager@beispiel-medizintechnik.de, set a new suggestion. (empty) -> "0". Event #20.
- 2026-10-08 21:39:26 UTC. ra.manager@beispiel-medizintechnik.de approved "0". Event #86.

**Device Name (FLD-UDID-22)**

- 2026-10-08 21:39:09 UTC. ra.manager@beispiel-medizintechnik.de approved "Zementfreier Hüftschaft Größe 3" in bulk review B-07A2C765. Event #69.

**Applicable Legislation (FLD-UDID-11)**

- 2026-10-08 21:39:09 UTC. ra.manager@beispiel-medizintechnik.de approved "MDR" in bulk review B-07A2C765. Event #69.

**Risk Class (FLD-UDID-16)**

- 2026-10-08 21:39:09 UTC. ra.manager@beispiel-medizintechnik.de approved "CLASS_III" in bulk review B-07A2C765. Event #69.

**Legal Manufacturer SRN (FLD-UDID-10)**

- 2026-10-08 21:39:09 UTC. ra.manager@beispiel-medizintechnik.de approved "DE-MF-000000042" in bulk review B-07A2C765. Event #69.

**Implantable (FLD-UDID-30)**

- 2026-10-08 21:39:09 UTC. ra.manager@beispiel-medizintechnik.de approved "true" in bulk review B-07A2C765. Event #69.

**Active Device (FLD-UDID-28)**

- 2026-10-08 21:39:09 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #69.

**Measuring Function (FLD-UDID-31)**

- 2026-10-08 21:39:09 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #69.

**Reusable Surgical Instruments (FLD-UDID-32)**

- 2026-10-08 21:39:09 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #69.

**Presence of animal tissues or cells (FLD-UDID-18)**

- 2026-10-08 21:39:09 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #69.

**Presence of human tissues or cells (FLD-UDID-23)**

- 2026-10-08 21:39:09 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #69.

**Device intended to administer medicinal product (FLD-UDID-29)**

- 2026-10-08 21:39:09 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #69.

**Substance - may be considered medicinal product (FLD-UDID-158)**

- 2026-10-08 21:39:09 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #69.

**Reference / Catalogue number (FLD-UDID-163)**

- 2026-10-08 21:39:09 UTC. ra.manager@beispiel-medizintechnik.de approved "ART-1003" in bulk review B-07A2C765. Event #69.

**Trade name (FLD-UDID-176)**

- 2026-10-08 21:39:09 UTC. ra.manager@beispiel-medizintechnik.de approved "DE: OrthoFlex Hip Stem Größe 3" in bulk review B-07A2C765. Event #69.

**UDI-DI code (FLD-UDID-178)**

- 2026-10-08 21:39:09 UTC. ra.manager@beispiel-medizintechnik.de approved "04011616010037" in bulk review B-07A2C765. Event #69.

**Device labelled sterile (FLD-UDID-169)**

- 2026-10-08 21:39:09 UTC. ra.manager@beispiel-medizintechnik.de approved "true" in bulk review B-07A2C765. Event #69.

**Need for sterilisation before use (FLD-UDID-170)**

- 2026-10-08 21:39:09 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #69.

**Labelled as single use (FLD-UDID-167)**

- 2026-10-08 21:39:09 UTC. ra.manager@beispiel-medizintechnik.de approved "true" in bulk review B-07A2C765. Event #69.

**Reprocessed single use device (FLD-UDID-164)**

- 2026-10-08 21:39:09 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #69.

**Containing latex (FLD-UDID-156)**

- 2026-10-08 21:39:09 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #69.

**Device Status (FLD-UDID-130)**

- 2026-10-08 21:39:09 UTC. ra.manager@beispiel-medizintechnik.de approved "ON_THE_MARKET" in bulk review B-07A2C765. Event #69.

**Type of UDI-PI (Production Identifier) (FLD-UDID-148)**

- 2026-10-08 21:39:09 UTC. ra.manager@beispiel-medizintechnik.de approved "SERIALISATION_NUMBER" in bulk review B-07A2C765. Event #69.

**Quantity of device (FLD-UDID-151)**

- 2026-10-08 21:39:09 UTC. ra.manager@beispiel-medizintechnik.de approved "1" in bulk review B-07A2C765. Event #69.

**Certificate Type (FLD-UDID-60)**

- 2026-10-08 21:39:09 UTC. ra.manager@beispiel-medizintechnik.de approved "MDR_TYPE_EXAMINATION" in bulk review B-07A2C765. Event #69.

**Certificate Number (FLD-UDID-61)**

- 2026-10-08 21:39:09 UTC. ra.manager@beispiel-medizintechnik.de approved "0123/2022/045678" in bulk review B-07A2C765. Event #69.

**Notified Body (Certificate) (FLD-UDID-63)**

- 2026-10-08 21:39:09 UTC. ra.manager@beispiel-medizintechnik.de approved "0123" in bulk review B-07A2C765. Event #69.

**Certificate Expiry Date (FLD-UDID-64)**

- 2026-10-08 21:39:09 UTC. ra.manager@beispiel-medizintechnik.de approved "2027-04-30" in bulk review B-07A2C765. Event #69.

**Member State where device is available (FLD-UDID-252)**

- 2026-10-08 21:39:09 UTC. ra.manager@beispiel-medizintechnik.de approved "DE,AT,FR,IT,ES,NL,BE,PL" in bulk review B-07A2C765. Event #69.

**Basic UDI-DI code (FLD-UDID-14)**

- 2026-10-08 21:39:09 UTC. ra.manager@beispiel-medizintechnik.de approved "401161600010X5" in bulk review B-07A2C765. Event #69.

**Substance - human blood or plasma derived (FLD-UDID-155)**

- 2026-10-08 21:39:09 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #69.

**Market Info Start date (FLD-UDID-250)**

- 2026-10-08 21:39:09 UTC. ra.manager@beispiel-medizintechnik.de approved "2023-06-15" in bulk review B-07A2C765. Event #69.

**Issuing Entity Basic UDI-DI (FLD-UDID-01)**

- 2026-10-08 21:39:09 UTC. ra.manager@beispiel-medizintechnik.de approved "GS1" in bulk review B-07A2C765. Event #69.

**Issuing Entity UDI-DI (FLD-UDID-291)**

- 2026-10-08 21:39:09 UTC. ra.manager@beispiel-medizintechnik.de approved "GS1" in bulk review B-07A2C765. Event #69.

**System/Procedure Pack Type (FLD-UDID-12)**

- 2026-10-08 21:39:09 UTC. ra.manager@beispiel-medizintechnik.de approved "DEVICE" in bulk review B-07A2C765. Event #69.

**Member State of first placing on EU market (FLD-UDID-137)**

- 2026-10-08 21:39:09 UTC. ra.manager@beispiel-medizintechnik.de approved "DE" in bulk review B-07A2C765. Event #69.

**Sterilisation method (FLD-UDID-165)**

- 2026-10-08 21:39:09 UTC. ra.manager@beispiel-medizintechnik.de approved "ETO" in bulk review B-07A2C765. Event #69.

## 5. Validation History

- At upload, 2026-10-08 21:38:03 UTC. The rule check found 1 error(s) for this device
  - Error BR-MANDATORY, FLD-UDID-149. The rule check reported "Mandatory field missing for MDR".
- At export, 2026-10-08 21:39:52 UTC. 0 error(s), 0 warning(s) for this device under MDR
  - Language of a text. Trade name (FLD-UDID-176) is DE. The language code was written before the text in the uploaded file.
  - Passed EUDAMED's XSD format check.
- **Final status:** PASSED at export (2026-10-08 21:39:52 UTC). No rule errors, 0 warning(s), XSD check passed.

## 6. Milestones

- **Snapshot at upload** by ra.manager@beispiel-medizintechnik.de at 2026-10-08 21:38:17 UTC
- **Snapshot at export** by ra.manager@beispiel-medizintechnik.de at 2026-10-08 21:39:53 UTC

## 7. Full Timeline

- 2026-10-08 21:38:01 UTC. **File uploaded.** sample_catalogue.csv, 14 rows
- 2026-10-08 21:38:02 UTC. **Columns mapped.** 38 of 40 columns mapped (95%)
- 2026-10-08 21:38:03 UTC. **Validation at upload.** 1 error(s) for this device

- 2026-10-08 21:38:16 UTC. **Legislation determined.** MDR, stated in the uploaded file (FLD-UDID-11 as supplied (MDR))
- 2026-10-08 21:38:17 UTC. **Snapshot.** Snapshot at upload, by ra.manager@beispiel-medizintechnik.de
- 2026-10-08 21:38:18 UTC. **Device imported.** 38 fields imported, event #18
- 2026-10-08 21:38:19 UTC. **AI EMDN suggestion.** AI suggested P090804010206 (45% confidence)
- 2026-10-08 21:38:20 UTC. **Field change.** 2 field change(s) by the AI classifier, event #20
- 2026-10-08 21:39:09 UTC. **Field change.** 36 field change(s) by ra.manager@beispiel-medizintechnik.de, event #69
- 2026-10-08 21:39:25 UTC. **Field change.** 1 field change(s) by ra.manager@beispiel-medizintechnik.de, event #85
- 2026-10-08 21:39:26 UTC. **Field change.** 1 field change(s) by ra.manager@beispiel-medizintechnik.de, event #86
- 2026-10-08 21:39:52 UTC. **Validation at export.** 0 error(s), 0 warning(s). XSD check passed
- 2026-10-08 21:39:53 UTC. **Snapshot.** Snapshot at export, by ra.manager@beispiel-medizintechnik.de

# Device ART-1004, UDI-DI 04011616010044, "Zementfreier Hüftschaft Größe 4"

**Reference number:** ART-1004
**Device UDI-DI:** 04011616010044
**Name:** Zementfreier Hüftschaft Größe 4
**Legislation:** MDR, stated in the uploaded file
**Reviewed by:** ra.manager@beispiel-medizintechnik.de on 2026-10-08 21:39:29 UTC
**Events in this record:** 14

## 1. Data Provenance

- **sample_catalogue.csv** (csv, 14 rows), uploaded 2026-10-08 21:38:01 UTC

## 2. Column Mapping

- Mapped: 38 of 40 columns (95%)
- By method: exact match 33, normalised name 1, alias 0, AI 4
- Mandatory fields with no source column at upload: Nomenclature code (EMDN)

## 3. EMDN Classification

- **Confirmed by reviewer, the AI suggestion:** P090804010207 (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH MODULAR NECK, ANATOMICAL), AI confidence 90%
  - AI reasoning: Description states 'zementfrei' (uncemented) and 'Hüftschaft' (hip stem), so the code is supported. Neck type is not stated. A second check by another model could not be completed, so the first answer is shown.
  - Other codes listed for comparison. Their search match is not the confidence printed above. P090804010201 (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH FIXED NECK, STRAIGHT) (search match 19%); P090804010202 (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH FIXED NECK, ANATOMICAL) (search match 65%); P090804010206 (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH MODULAR NECK, STRAIGHT) (search match 65%); P090804030201 (REVISION UNCEMENTED FEMORAL STEMS, WITH FIXED NECK) (search match 62%)

## 3.5 Field-Level Reasoning

Each value below shows the source column, rule, reviewer action or AI rationale that produced it.

| Field | Value | Status | Source | Confidence | Reasoning |
|---|---|---|---|---|---|
| Device Name (FLD-UDID-22) | Zementfreier Hüftschaft Größe 4 | Approved | Exact column match, approved in a bulk review | 100% | Column "Bezeichnung" matched "Device Name" exactly. |
| Applicable Legislation (FLD-UDID-11) | MDR | Approved | Exact column match, approved in a bulk review | 100% | Column "Rechtsgrundlage" matched "Applicable Legislation" exactly. |

| Field | Value | Status | Source | Confidence | Reasoning |
|---|---|---|---|---|---|
| Risk Class (FLD-UDID-16) | Class III (CLASS_III) | Approved | Exact column match, approved in a bulk review | 100% | Column "Risikoklasse" matched "Risk Class" exactly. |
| Legal Manufacturer SRN (FLD-UDID-10) | DE-MF-000000042 | Approved | Exact column match, approved in a bulk review | 100% | Column "Hersteller-SRN" matched "Legal Manufacturer SRN" exactly. |
| Implantable (FLD-UDID-30) | true | Approved | Exact column match, approved in a bulk review | 100% | Column "Implantierbar" matched "Implantable" exactly. |
| Active Device (FLD-UDID-28) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Aktives Medizinprodukt" matched "Active Device" exactly. |
| Measuring Function (FLD-UDID-31) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Messfunktion" matched "Measuring Function" exactly. |
| Reusable Surgical Instruments (FLD-UDID-32) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Wiederverwendbar" matched "Reusable Surgical Instruments" exactly. |
| Presence of animal tissues or cells (FLD-UDID-18) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Tierisches Gewebe" matched "Presence of animal tissues or cells" exactly. |
| Presence of human tissues or cells (FLD-UDID-23) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Menschliches Gewebe" matched "Presence of human tissues or cells" exactly. |
| Device intended to administer medicinal product (FLD-UDID-29) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Arzneimittelabgabe" matched "Device intended to administer medicinal product" exactly. |
| Substance - may be considered medicinal product (FLD-UDID-158) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Arzneimittel" matched "Substance - may be considered medicinal product" exactly. |
| Reference / Catalogue number (FLD-UDID-163) | ART-1004 | Approved | Exact column match, approved in a bulk review | 100% | Column "Artikelnummer" matched "Reference / Catalogue number" exactly. |
| Trade name (FLD-UDID-176) | DE: OrthoFlex Hip Stem Größe 4 | Approved | Exact column match, approved in a bulk review | 100% | Column "Handelsname" matched "Trade name" exactly. |
| UDI-DI code (FLD-UDID-178) | 04011616010044 | Approved | Exact column match, approved in a bulk review | 100% | Column "GTIN" matched "UDI-DI code" exactly. |
| Device labelled sterile (FLD-UDID-169) | true | Approved | Exact column match, approved in a bulk review | 100% | Column "Steril" matched "Device labelled sterile" exactly. |

| Field | Value | Status | Source | Confidence | Reasoning |
|---|---|---|---|---|---|
| Need for sterilisation before use (FLD-UDID-170) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Sterilisation" matched "Need for sterilisation before use" exactly. |
| Labelled as single use (FLD-UDID-167) | true | Approved | Exact column match, approved in a bulk review | 100% | Column "Einmalgebrauch" matched "Labelled as single use" exactly. |
| Reprocessed single use device (FLD-UDID-164) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Aufbereitet" matched "Reprocessed single use device" exactly. |
| Containing latex (FLD-UDID-156) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Enthält Latex" matched "Containing latex" exactly. |
| Device Status (FLD-UDID-130) | On the market (ON_THE_MARKET) | Approved | Exact column match, approved in a bulk review | 100% | Column "Marktstatus" matched "Device Status" exactly. |
| Type of UDI-PI (Production Identifier) (FLD-UDID-148) | Serialisation number (SERIALISATION_NUMBER) | Approved | Exact column match, approved in a bulk review | 100% | Column "UDI-PI Typ" matched "Type of UDI-PI (Production Identifier)" exactly. |
| Quantity of device (FLD-UDID-151) | 1 | Approved | Exact column match, approved in a bulk review | 100% | Column "Menge" matched "Quantity of device" exactly. |
| Certificate Type (FLD-UDID-60) | MDR type examination (MDR_TYPE_EXAMINATION) | Approved | Exact column match, approved in a bulk review | 100% | Column "Zertifikattyp" matched "Certificate Type" exactly. |
| Certificate Number (FLD-UDID-61) | 0123/2022/045678 | Approved | Exact column match, approved in a bulk review | 100% | Column "Zertifikatsnummer" matched "Certificate Number" exactly. |
| Notified Body (Certificate) (FLD-UDID-63) | 0123 | Approved | Exact column match, approved in a bulk review | 100% | Column "Benannte Stelle" matched "Notified Body (Certificate)" exactly. |
| Certificate Expiry Date (FLD-UDID-64) | 2027-04-30 | Approved | Exact column match, approved in a bulk review | 100% | Column "Ablaufdatum Zertifikat" matched "Certificate Expiry Date" exactly. |
| Member State where device is available (FLD-UDID-252) | DE,AT,FR,IT,ES,NL,BE,PL | Approved | Exact column match, approved in a bulk review | 100% | Column "Vertriebsland" matched "Member State where device is available" exactly. |
| Basic UDI-DI code (FLD-UDID-14) | 401161600010X5 | Approved | Column match after normalising the name, approved in a bulk review | 95% | Column "Basic-UDI-DI" matched "Basic UDI-DI code" after normalising punctuation/case. |
| Substance - human blood or plasma derived (FLD-UDID-155) | false | Approved | AI column mapping, approved in a bulk review | 95% | AI mapped column "Blut- oder Plasmaderivat" to "Substance - human blood or plasma derived" (confidence 0.95). German for human blood or plasma derived substance |

| Field | Value | Status | Source | Confidence | Reasoning |
|---|---|---|---|---|---|
| Market Info Start date (FLD-UDID-250) | 2023-06-15 | Approved | AI column mapping, approved in a bulk review | 90% | AI mapped column "Marktverfügbarkeit ab" to "Market Info Start date" (confidence 0.90). Complements mapped Member State availability |
| Issuing Entity Basic UDI-DI (FLD-UDID-01) | GS1 | Approved | Derived by rule, approved in a bulk review | 100% | Inferred from Basic UDI-DI code format, "401161600010X5" is a GS1 identifier. |
| Issuing Entity UDI-DI (FLD-UDID-291) | GS1 | Approved | Derived by rule, approved in a bulk review | 100% | Inferred from UDI-DI code format, "04011616010044" is a GS1 identifier. |
| System/Procedure Pack Type (FLD-UDID-12) | DEVICE | Approved | Declared by the customer, approved in a bulk review | 100% | Declared at project level by the project owner: every device in this project is a device in itself, not a system or a procedure pack (MDR Art. 22). EUDAMED field FLD-UDID-12. |
| Member State of first placing on EU market (FLD-UDID-137) | DE | Approved | Declared by the customer, approved in a bulk review | 100% | Declared at project level by the project owner: the devices in this project were first placed on the EU market in DE. EUDAMED field FLD-UDID-137. |
| Nomenclature code (EMDN) (FLD-UDID-149) | P090804010207 (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH MODULAR NECK, ANATOMICAL) | Approved | AI suggestion, approved by reviewer | 90% | Description states 'zementfrei' (uncemented) and 'Hüftschaft' (hip stem), so the code is supported. Neck type is not stated. A second check by another model could not be completed, so the first answer is shown. |
| Maximum number of reuses (FLD-UDID-157) | 0 | Approved | Derived by rule, approved by reviewer | 100% | Derived: device is labelled single use (FLD-UDID-167 = true), so maximum reuses is 0. |
| Sterilisation method (FLD-UDID-165) | (empty) | Left empty by reviewer | Exact column match, left empty by reviewer | 100% | Column "Sterilisationsverfahren" matched "Sterilisation method" exactly. |

## 4. Human Overrides

No override by a reviewer was recorded. Section 4.1 lists every recorded change to this device, including approvals and other edits.

## 4.1 Change history

The device was imported at 2026-10-08 21:38:23 UTC with 38 fields (event #23). Each line is one recorded change, oldest first. The event number is its position in this project's audit trail.

**Nomenclature code (EMDN) (FLD-UDID-149)**

- 2026-10-08 21:38:25 UTC. The AI classifier, run by ra.manager@beispiel-medizintechnik.de, set a new suggestion. (empty) -> "P090804010207" (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH MODULAR NECK, ANATOMICAL). Event #25.
- 2026-10-08 21:39:27 UTC. ra.manager@beispiel-medizintechnik.de approved "P090804010207" (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH MODULAR NECK, ANATOMICAL). The AI had suggested "P090804010207" (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH MODULAR NECK, ANATOMICAL) with 90% confidence in event #24. Event #87.

**Maximum number of reuses (FLD-UDID-157)**

- 2026-10-08 21:38:25 UTC. The AI classifier, run by ra.manager@beispiel-medizintechnik.de, set a new suggestion. (empty) -> "0". Event #25.
- 2026-10-08 21:39:28 UTC. ra.manager@beispiel-medizintechnik.de approved "0". Event #88.

**Device Name (FLD-UDID-22)**

- 2026-10-08 21:39:10 UTC. ra.manager@beispiel-medizintechnik.de approved "Zementfreier Hüftschaft Größe 4" in bulk review B-07A2C765. Event #70.

**Applicable Legislation (FLD-UDID-11)**

- 2026-10-08 21:39:10 UTC. ra.manager@beispiel-medizintechnik.de approved "MDR" in bulk review B-07A2C765. Event #70.

**Risk Class (FLD-UDID-16)**

- 2026-10-08 21:39:10 UTC. ra.manager@beispiel-medizintechnik.de approved "CLASS_III" in bulk review B-07A2C765. Event #70.

**Legal Manufacturer SRN (FLD-UDID-10)**

- 2026-10-08 21:39:10 UTC. ra.manager@beispiel-medizintechnik.de approved "DE-MF-000000042" in bulk review B-07A2C765. Event #70.

**Implantable (FLD-UDID-30)**

- 2026-10-08 21:39:10 UTC. ra.manager@beispiel-medizintechnik.de approved "true" in bulk review B-07A2C765. Event #70.

**Active Device (FLD-UDID-28)**

- 2026-10-08 21:39:10 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #70.

**Measuring Function (FLD-UDID-31)**

- 2026-10-08 21:39:10 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #70.

**Reusable Surgical Instruments (FLD-UDID-32)**

- 2026-10-08 21:39:10 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #70.

**Presence of animal tissues or cells (FLD-UDID-18)**

- 2026-10-08 21:39:10 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #70.

**Presence of human tissues or cells (FLD-UDID-23)**

- 2026-10-08 21:39:10 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #70.

**Device intended to administer medicinal product (FLD-UDID-29)**

- 2026-10-08 21:39:10 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #70.

**Substance - may be considered medicinal product (FLD-UDID-158)**

- 2026-10-08 21:39:10 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #70.

**Reference / Catalogue number (FLD-UDID-163)**

- 2026-10-08 21:39:10 UTC. ra.manager@beispiel-medizintechnik.de approved "ART-1004" in bulk review B-07A2C765. Event #70.

**Trade name (FLD-UDID-176)**

- 2026-10-08 21:39:10 UTC. ra.manager@beispiel-medizintechnik.de approved "DE: OrthoFlex Hip Stem Größe 4" in bulk review B-07A2C765. Event #70.

**UDI-DI code (FLD-UDID-178)**

- 2026-10-08 21:39:10 UTC. ra.manager@beispiel-medizintechnik.de approved "04011616010044" in bulk review B-07A2C765. Event #70.

**Device labelled sterile (FLD-UDID-169)**

- 2026-10-08 21:39:10 UTC. ra.manager@beispiel-medizintechnik.de approved "true" in bulk review B-07A2C765. Event #70.

**Need for sterilisation before use (FLD-UDID-170)**

- 2026-10-08 21:39:10 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #70.

**Labelled as single use (FLD-UDID-167)**

- 2026-10-08 21:39:10 UTC. ra.manager@beispiel-medizintechnik.de approved "true" in bulk review B-07A2C765. Event #70.

**Reprocessed single use device (FLD-UDID-164)**

- 2026-10-08 21:39:10 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #70.

**Containing latex (FLD-UDID-156)**

- 2026-10-08 21:39:10 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #70.

**Device Status (FLD-UDID-130)**

- 2026-10-08 21:39:10 UTC. ra.manager@beispiel-medizintechnik.de approved "ON_THE_MARKET" in bulk review B-07A2C765. Event #70.

**Type of UDI-PI (Production Identifier) (FLD-UDID-148)**

- 2026-10-08 21:39:10 UTC. ra.manager@beispiel-medizintechnik.de approved "SERIALISATION_NUMBER" in bulk review B-07A2C765. Event #70.

**Quantity of device (FLD-UDID-151)**

- 2026-10-08 21:39:10 UTC. ra.manager@beispiel-medizintechnik.de approved "1" in bulk review B-07A2C765. Event #70.

**Certificate Type (FLD-UDID-60)**

- 2026-10-08 21:39:10 UTC. ra.manager@beispiel-medizintechnik.de approved "MDR_TYPE_EXAMINATION" in bulk review B-07A2C765. Event #70.

**Certificate Number (FLD-UDID-61)**

- 2026-10-08 21:39:10 UTC. ra.manager@beispiel-medizintechnik.de approved "0123/2022/045678" in bulk review B-07A2C765. Event #70.

**Notified Body (Certificate) (FLD-UDID-63)**

- 2026-10-08 21:39:10 UTC. ra.manager@beispiel-medizintechnik.de approved "0123" in bulk review B-07A2C765. Event #70.

**Certificate Expiry Date (FLD-UDID-64)**

- 2026-10-08 21:39:10 UTC. ra.manager@beispiel-medizintechnik.de approved "2027-04-30" in bulk review B-07A2C765. Event #70.

**Member State where device is available (FLD-UDID-252)**

- 2026-10-08 21:39:10 UTC. ra.manager@beispiel-medizintechnik.de approved "DE,AT,FR,IT,ES,NL,BE,PL" in bulk review B-07A2C765. Event #70.

**Basic UDI-DI code (FLD-UDID-14)**

- 2026-10-08 21:39:10 UTC. ra.manager@beispiel-medizintechnik.de approved "401161600010X5" in bulk review B-07A2C765. Event #70.

**Substance - human blood or plasma derived (FLD-UDID-155)**

- 2026-10-08 21:39:10 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #70.

**Market Info Start date (FLD-UDID-250)**

- 2026-10-08 21:39:10 UTC. ra.manager@beispiel-medizintechnik.de approved "2023-06-15" in bulk review B-07A2C765. Event #70.

**Issuing Entity Basic UDI-DI (FLD-UDID-01)**

- 2026-10-08 21:39:10 UTC. ra.manager@beispiel-medizintechnik.de approved "GS1" in bulk review B-07A2C765. Event #70.

**Issuing Entity UDI-DI (FLD-UDID-291)**

- 2026-10-08 21:39:10 UTC. ra.manager@beispiel-medizintechnik.de approved "GS1" in bulk review B-07A2C765. Event #70.

**System/Procedure Pack Type (FLD-UDID-12)**

- 2026-10-08 21:39:10 UTC. ra.manager@beispiel-medizintechnik.de approved "DEVICE" in bulk review B-07A2C765. Event #70.

**Member State of first placing on EU market (FLD-UDID-137)**

- 2026-10-08 21:39:10 UTC. ra.manager@beispiel-medizintechnik.de approved "DE" in bulk review B-07A2C765. Event #70.

**Sterilisation method (FLD-UDID-165)**

- 2026-10-08 21:39:29 UTC. ra.manager@beispiel-medizintechnik.de left the field empty. Event #89.

## 5. Validation History

- At upload, 2026-10-08 21:38:03 UTC. The rule check found 1 error(s) for this device
  - Error BR-MANDATORY, FLD-UDID-149. The rule check reported "Mandatory field missing for MDR".
- At export, 2026-10-08 21:39:54 UTC. 0 error(s), 0 warning(s) for this device under MDR
  - Language of a text. Trade name (FLD-UDID-176) is DE. The language code was written before the text in the uploaded file.
  - Passed EUDAMED's XSD format check.
- **Final status:** PASSED at export (2026-10-08 21:39:54 UTC). No rule errors, 0 warning(s), XSD check passed.

## 6. Milestones

- **Snapshot at upload** by ra.manager@beispiel-medizintechnik.de at 2026-10-08 21:38:22 UTC
- **Snapshot at export** by ra.manager@beispiel-medizintechnik.de at 2026-10-08 21:39:55 UTC

## 7. Full Timeline

- 2026-10-08 21:38:01 UTC. **File uploaded.** sample_catalogue.csv, 14 rows
- 2026-10-08 21:38:02 UTC. **Columns mapped.** 38 of 40 columns mapped (95%)
- 2026-10-08 21:38:03 UTC. **Validation at upload.** 1 error(s) for this device
- 2026-10-08 21:38:21 UTC. **Legislation determined.** MDR, stated in the uploaded file (FLD-UDID-11 as supplied (MDR))
- 2026-10-08 21:38:22 UTC. **Snapshot.** Snapshot at upload, by ra.manager@beispiel-medizintechnik.de
- 2026-10-08 21:38:23 UTC. **Device imported.** 38 fields imported, event #23
- 2026-10-08 21:38:24 UTC. **AI EMDN suggestion.** AI suggested P090804010207 (90% confidence)

- 2026-10-08 21:38:25 UTC. **Field change.** 2 field change(s) by the AI classifier, event #25
- 2026-10-08 21:39:10 UTC. **Field change.** 35 field change(s) by ra.manager@beispiel-medizintechnik.de, event #70
- 2026-10-08 21:39:27 UTC. **Field change.** 1 field change(s) by ra.manager@beispiel-medizintechnik.de, event #87
- 2026-10-08 21:39:28 UTC. **Field change.** 1 field change(s) by ra.manager@beispiel-medizintechnik.de, event #88
- 2026-10-08 21:39:29 UTC. **Field change.** 1 field change(s) by ra.manager@beispiel-medizintechnik.de, event #89
- 2026-10-08 21:39:54 UTC. **Validation at export.** 0 error(s), 0 warning(s). XSD check passed
- 2026-10-08 21:39:55 UTC. **Snapshot.** Snapshot at export, by ra.manager@beispiel-medizintechnik.de

# Device ART-1005, UDI-DI 04011616010051, "Zementfreier Hüftschaft Größe 5"

**Reference number:** ART-1005
**Device UDI-DI:** 04011616010051
**Name:** Zementfreier Hüftschaft Größe 5
**Legislation:** MDR, stated in the uploaded file
**Reviewed by:** ra.manager@beispiel-medizintechnik.de on 2026-10-08 21:39:31 UTC
**Events in this record:** 13

## 1. Data Provenance

- **sample_catalogue.csv** (csv, 14 rows), uploaded 2026-10-08 21:38:01 UTC

## 2. Column Mapping

- Mapped: 38 of 40 columns (95%)
- By method: exact match 33, normalised name 1, alias 0, AI 4
- Mandatory fields with no source column at upload: Nomenclature code (EMDN)

## 3. EMDN Classification

- **Confirmed by reviewer, the AI suggestion:** P090804030201 (REVISION UNCEMENTED FEMORAL STEMS, WITH FIXED NECK), AI confidence 65%
  - AI reasoning: The description's own words did not point to P090804030201. Similar devices registered in EUDAMED use this code (5 manufacturers, 334 registrations, 22% of filings, registered name similar in meaning to "quill pdo quill pdo polydioxanone"). Same product family, USP 3-0. A second check by another model could not be completed, so the first answer is shown.
  - Other codes listed for comparison. Their search match is not the confidence printed above. P090804010201 (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH FIXED NECK, STRAIGHT) (search match 19%); P090804010202 (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH FIXED NECK, ANATOMICAL) (search match 65%); P090804010206 (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH MODULAR NECK, STRAIGHT) (search match 65%); P090804010207 (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH MODULAR NECK, ANATOMICAL) (search match 62%)

## 3.5 Field-Level Reasoning

Each value below shows the source column, rule, reviewer action or AI rationale that produced it.

| Field | Value | Status | Source | Confidence | Reasoning |
|---|---|---|---|---|---|
| Device Name (FLD-UDID-22) | Zementfreier Hüftschaft Größe 5 | Approved | Exact column match, approved in a bulk review | 100% | Column "Bezeichnung" matched "Device Name" exactly. |
| Applicable Legislation (FLD-UDID-11) | MDR | Approved | Exact column match, approved in a bulk review | 100% | Column "Rechtsgrundlage" matched "Applicable Legislation" exactly. |
| Risk Class (FLD-UDID-16) | Class III (CLASS_III) | Approved | Exact column match, approved in a bulk review | 100% | Column "Risikoklasse" matched "Risk Class" exactly. |
| Legal Manufacturer SRN (FLD-UDID-10) | DE-MF-000000042 | Approved | Exact column match, approved in a bulk review | 100% | Column "Hersteller-SRN" matched "Legal Manufacturer SRN" exactly. |
| Implantable (FLD-UDID-30) | true | Approved | Exact column match, approved in a bulk review | 100% | Column "Implantierbar" matched "Implantable" exactly. |
| Active Device (FLD-UDID-28) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Aktives Medizinprodukt" matched "Active Device" exactly. |
| Measuring Function (FLD-UDID-31) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Messfunktion" matched "Measuring Function" exactly. |
| Reusable Surgical Instruments (FLD-UDID-32) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Wiederverwendbar" matched "Reusable Surgical Instruments" exactly. |
| Presence of animal tissues or cells (FLD-UDID-18) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Tierisches Gewebe" matched "Presence of animal tissues or cells" exactly. |
| Presence of human tissues or cells (FLD-UDID-23) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Menschliches Gewebe" matched "Presence of human tissues or cells" exactly. |
| Device intended to administer medicinal product (FLD-UDID-29) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Arzneimittelabgabe" matched "Device intended to administer medicinal product" exactly. |
| Substance - may be considered medicinal product (FLD-UDID-158) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Arzneimittel" matched "Substance - may be considered medicinal product" exactly. |
| Reference / Catalogue number (FLD-UDID-163) | ART-1005 | Approved | Exact column match, approved in a bulk review | 100% | Column "Artikelnummer" matched "Reference / Catalogue number" exactly. |

| Field | Value | Status | Source | Confidence | Reasoning |
|---|---|---|---|---|---|
| Trade name (FLD-UDID-176) | DE: OrthoFlex Hip Stem Größe 5 | Approved | Exact column match, approved in a bulk review | 100% | Column "Handelsname" matched "Trade name" exactly. |
| UDI-DI code (FLD-UDID-178) | 04011616010051 | Approved | Exact column match, approved in a bulk review | 100% | Column "GTIN" matched "UDI-DI code" exactly. |
| Device labelled sterile (FLD-UDID-169) | true | Approved | Exact column match, approved in a bulk review | 100% | Column "Steril" matched "Device labelled sterile" exactly. |
| Need for sterilisation before use (FLD-UDID-170) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Sterilisation" matched "Need for sterilisation before use" exactly. |
| Labelled as single use (FLD-UDID-167) | true | Approved | Exact column match, approved in a bulk review | 100% | Column "Einmalgebrauch" matched "Labelled as single use" exactly. |
| Reprocessed single use device (FLD-UDID-164) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Aufbereitet" matched "Reprocessed single use device" exactly. |
| Containing latex (FLD-UDID-156) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Enthält Latex" matched "Containing latex" exactly. |
| Device Status (FLD-UDID-130) | On the market (ON_THE_MARKET) | Approved | Exact column match, approved in a bulk review | 100% | Column "Marktstatus" matched "Device Status" exactly. |
| Type of UDI-PI (Production Identifier) (FLD-UDID-148) | Serialisation number (SERIALISATION_NUMBER) | Approved | Exact column match, approved in a bulk review | 100% | Column "UDI-PI Typ" matched "Type of UDI-PI (Production Identifier)" exactly. |
| Quantity of device (FLD-UDID-151) | 1 | Approved | Exact column match, approved in a bulk review | 100% | Column "Menge" matched "Quantity of device" exactly. |
| Certificate Type (FLD-UDID-60) | MDR type examination (MDR_TYPE_EXAMINATION) | Approved | Exact column match, approved in a bulk review | 100% | Column "Zertifikattyp" matched "Certificate Type" exactly. |
| Certificate Number (FLD-UDID-61) | 0123/2022/045678 | Approved | Exact column match, approved in a bulk review | 100% | Column "Zertifikatsnummer" matched "Certificate Number" exactly. |
| Notified Body (Certificate) (FLD-UDID-63) | 0434 | Approved | Exact column match, approved in a bulk review | 100% | Column "Benannte Stelle" matched "Notified Body (Certificate)" exactly. |
| Certificate Expiry Date (FLD-UDID-64) | 2027-04-30 | Approved | Exact column match, approved in a bulk review | 100% | Column "Ablaufdatum Zertifikat" matched "Certificate Expiry Date" exactly. |
| Member State where device is available (FLD-UDID-252) | DE,AT,FR,IT,ES,NL,BE,PL | Approved | Exact column match, approved in a bulk review | 100% | Column "Vertriebsland" matched "Member State where device is available" exactly. |
| Basic UDI-DI code (FLD-UDID-14) | 401161600010X5 | Approved | Column match after normalising the name, approved in a bulk review | 95% | Column "Basic-UDI-DI" matched "Basic UDI-DI code" after normalising punctuation/case. |

| Field | Value | Status | Source | Confidence | Reasoning |
|---|---|---|---|---|---|
| Substance - human blood or plasma derived (FLD-UDID-155) | false | Approved | AI column mapping, approved in a bulk review | 95% | AI mapped column "Blut- oder Plasmaderivat" to "Substance - human blood or plasma derived" (confidence 0.95). German for human blood or plasma derived substance |
| Market Info Start date (FLD-UDID-250) | 2023-06-15 | Approved | AI column mapping, approved in a bulk review | 90% | AI mapped column "Marktverfügbarkeit ab" to "Market Info Start date" (confidence 0.90). Complements mapped Member State availability |
| Issuing Entity Basic UDI-DI (FLD-UDID-01) | GS1 | Approved | Derived by rule, approved in a bulk review | 100% | Inferred from Basic UDI-DI code format, "401161600010X5" is a GS1 identifier. |
| Issuing Entity UDI-DI (FLD-UDID-291) | GS1 | Approved | Derived by rule, approved in a bulk review | 100% | Inferred from UDI-DI code format, "04011616010051" is a GS1 identifier. |
| System/Procedure Pack Type (FLD-UDID-12) | DEVICE | Approved | Declared by the customer, approved in a bulk review | 100% | Declared at project level by the project owner: every device in this project is a device in itself, not a system or a procedure pack (MDR Art. 22). EUDAMED field FLD-UDID-12. |
| Member State of first placing on EU market (FLD-UDID-137) | DE | Approved | Declared by the customer, approved in a bulk review | 100% | Declared at project level by the project owner: the devices in this project were first placed on the EU market in DE. EUDAMED field FLD-UDID-137. |
| Nomenclature code (EMDN) (FLD-UDID-149) | P090804030201 (REVISION UNCEMENTED FEMORAL STEMS, WITH FIXED NECK) | Approved | AI suggestion, approved by reviewer | 65% | The description's own words did not point to P090804030201. Similar devices registered in EUDAMED use this code (5 manufacturers, 334 registrations, 22% of filings, registered name similar in meaning to "quill pdo quill pdo polydioxanone"). Same product family, USP 3-0. A second check by another model could not be completed, so the first answer is shown. |
| Maximum number of reuses (FLD-UDID-157) | 0 | Approved | Derived by rule, approved by reviewer | 100% | Derived: device is labelled single use (FLD-UDID-167 = true), so maximum reuses is 0. |

| Field | Value | Status | Source | Confidence | Reasoning |
|---|---|---|---|---|---|
| Sterilisation method (FLD-UDID-165) | ETO | Approved | Exact column match, approved in a bulk review | 100% | Column "Sterilisationsverfahren" matched "Sterilisation method" exactly. |

## 4. Human Overrides

No override by a reviewer was recorded. Section 4.1 lists every recorded change to this device, including approvals and other edits.

## 4.1 Change history

The device was imported at 2026-10-08 21:38:28 UTC with 38 fields (event #28). Each line is one recorded change, oldest first. The event number is its position in this project's audit trail.

**Nomenclature code (EMDN) (FLD-UDID-149)**

- 2026-10-08 21:38:30 UTC. The AI classifier, run by ra.manager@beispiel-medizintechnik.de, set a new suggestion. (empty) -> "P090804030201" (REVISION UNCEMENTED FEMORAL STEMS, WITH FIXED NECK). Event #30.
- 2026-10-08 21:39:30 UTC. ra.manager@beispiel-medizintechnik.de approved "P090804030201" (REVISION UNCEMENTED FEMORAL STEMS, WITH FIXED NECK). The AI had suggested "P090804030201" (REVISION UNCEMENTED FEMORAL STEMS, WITH FIXED NECK) with 65% confidence in event #29. Event #90.

**Maximum number of reuses (FLD-UDID-157)**

- 2026-10-08 21:38:30 UTC. The AI classifier, run by ra.manager@beispiel-medizintechnik.de, set a new suggestion. (empty) -> "0". Event #30.
- 2026-10-08 21:39:31 UTC. ra.manager@beispiel-medizintechnik.de approved "0". Event #91.

**Device Name (FLD-UDID-22)**

- 2026-10-08 21:39:11 UTC. ra.manager@beispiel-medizintechnik.de approved "Zementfreier Hüftschaft Größe 5" in bulk review B-07A2C765. Event #71.

**Applicable Legislation (FLD-UDID-11)**

- 2026-10-08 21:39:11 UTC. ra.manager@beispiel-medizintechnik.de approved "MDR" in bulk review B-07A2C765. Event #71.

**Risk Class (FLD-UDID-16)**

- 2026-10-08 21:39:11 UTC. ra.manager@beispiel-medizintechnik.de approved "CLASS_III" in bulk review B-07A2C765. Event #71.

**Legal Manufacturer SRN (FLD-UDID-10)**

- 2026-10-08 21:39:11 UTC. ra.manager@beispiel-medizintechnik.de approved "DE-MF-000000042" in bulk review B-07A2C765. Event #71.

**Implantable (FLD-UDID-30)**

- 2026-10-08 21:39:11 UTC. ra.manager@beispiel-medizintechnik.de approved "true" in bulk review B-07A2C765. Event #71.

**Active Device (FLD-UDID-28)**

- 2026-10-08 21:39:11 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #71.

**Measuring Function (FLD-UDID-31)**

- 2026-10-08 21:39:11 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #71.

**Reusable Surgical Instruments (FLD-UDID-32)**

- 2026-10-08 21:39:11 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #71.

**Presence of animal tissues or cells (FLD-UDID-18)**

- 2026-10-08 21:39:11 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #71.

**Presence of human tissues or cells (FLD-UDID-23)**

- 2026-10-08 21:39:11 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #71.

**Device intended to administer medicinal product (FLD-UDID-29)**

- 2026-10-08 21:39:11 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #71.

**Substance - may be considered medicinal product (FLD-UDID-158)**

- 2026-10-08 21:39:11 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #71.

**Reference / Catalogue number (FLD-UDID-163)**

- 2026-10-08 21:39:11 UTC. ra.manager@beispiel-medizintechnik.de approved "ART-1005" in bulk review B-07A2C765. Event #71.

**Trade name (FLD-UDID-176)**

- 2026-10-08 21:39:11 UTC. ra.manager@beispiel-medizintechnik.de approved "DE: OrthoFlex Hip Stem Größe 5" in bulk review B-07A2C765. Event #71.

**UDI-DI code (FLD-UDID-178)**

- 2026-10-08 21:39:11 UTC. ra.manager@beispiel-medizintechnik.de approved "04011616010051" in bulk review B-07A2C765. Event #71.

**Device labelled sterile (FLD-UDID-169)**

- 2026-10-08 21:39:11 UTC. ra.manager@beispiel-medizintechnik.de approved "true" in bulk review B-07A2C765. Event #71.

**Need for sterilisation before use (FLD-UDID-170)**

- 2026-10-08 21:39:11 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #71.

**Labelled as single use (FLD-UDID-167)**

- 2026-10-08 21:39:11 UTC. ra.manager@beispiel-medizintechnik.de approved "true" in bulk review B-07A2C765. Event #71.

**Reprocessed single use device (FLD-UDID-164)**

- 2026-10-08 21:39:11 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #71.

**Containing latex (FLD-UDID-156)**

- 2026-10-08 21:39:11 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #71.

**Device Status (FLD-UDID-130)**

- 2026-10-08 21:39:11 UTC. ra.manager@beispiel-medizintechnik.de approved "ON_THE_MARKET" in bulk review B-07A2C765. Event #71.

**Type of UDI-PI (Production Identifier) (FLD-UDID-148)**

- 2026-10-08 21:39:11 UTC. ra.manager@beispiel-medizintechnik.de approved "SERIALISATION_NUMBER" in bulk review B-07A2C765. Event #71.

**Quantity of device (FLD-UDID-151)**

- 2026-10-08 21:39:11 UTC. ra.manager@beispiel-medizintechnik.de approved "1" in bulk review B-07A2C765. Event #71.

**Certificate Type (FLD-UDID-60)**

- 2026-10-08 21:39:11 UTC. ra.manager@beispiel-medizintechnik.de approved "MDR_TYPE_EXAMINATION" in bulk review B-07A2C765. Event #71.

**Certificate Number (FLD-UDID-61)**

- 2026-10-08 21:39:11 UTC. ra.manager@beispiel-medizintechnik.de approved "0123/2022/045678" in bulk review B-07A2C765. Event #71.

**Notified Body (Certificate) (FLD-UDID-63)**

- 2026-10-08 21:39:11 UTC. ra.manager@beispiel-medizintechnik.de approved "0434" in bulk review B-07A2C765. Event #71.

**Certificate Expiry Date (FLD-UDID-64)**

- 2026-10-08 21:39:11 UTC. ra.manager@beispiel-medizintechnik.de approved "2027-04-30" in bulk review B-07A2C765. Event #71.

**Member State where device is available (FLD-UDID-252)**

- 2026-10-08 21:39:11 UTC. ra.manager@beispiel-medizintechnik.de approved "DE,AT,FR,IT,ES,NL,BE,PL" in bulk review B-07A2C765. Event #71.

**Basic UDI-DI code (FLD-UDID-14)**

- 2026-10-08 21:39:11 UTC. ra.manager@beispiel-medizintechnik.de approved "401161600010X5" in bulk review B-07A2C765. Event #71.

**Substance - human blood or plasma derived (FLD-UDID-155)**

- 2026-10-08 21:39:11 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #71.

**Market Info Start date (FLD-UDID-250)**

- 2026-10-08 21:39:11 UTC. ra.manager@beispiel-medizintechnik.de approved "2023-06-15" in bulk review B-07A2C765. Event #71.

**Issuing Entity Basic UDI-DI (FLD-UDID-01)**

- 2026-10-08 21:39:11 UTC. ra.manager@beispiel-medizintechnik.de approved "GS1" in bulk review B-07A2C765. Event #71.

**Issuing Entity UDI-DI (FLD-UDID-291)**

- 2026-10-08 21:39:11 UTC. ra.manager@beispiel-medizintechnik.de approved "GS1" in bulk review B-07A2C765. Event #71.

**System/Procedure Pack Type (FLD-UDID-12)**

- 2026-10-08 21:39:11 UTC. ra.manager@beispiel-medizintechnik.de approved "DEVICE" in bulk review B-07A2C765. Event #71.

**Member State of first placing on EU market (FLD-UDID-137)**

- 2026-10-08 21:39:11 UTC. ra.manager@beispiel-medizintechnik.de approved "DE" in bulk review B-07A2C765. Event #71.

**Sterilisation method (FLD-UDID-165)**

- 2026-10-08 21:39:11 UTC. ra.manager@beispiel-medizintechnik.de approved "ETO" in bulk review B-07A2C765. Event #71.

## 5. Validation History

- At upload, 2026-10-08 21:38:03 UTC. The rule check found 1 error(s) for this device
  - Error BR-MANDATORY, FLD-UDID-149. The rule check reported "Mandatory field missing for MDR".
- At export, 2026-10-08 21:39:56 UTC. 0 error(s), 1 warning(s) for this device under MDR
  - Warning pre-export check, FLD-UDID-63. The rule check reported "Notified Body code "0434" is not in the NANDO registry of designated notified bodies. Confirm the notified body before submission.".
  - Language of a text. Trade name (FLD-UDID-176) is DE. The language code was written before the text in the uploaded file.
  - Passed EUDAMED's XSD format check.
- **Final status:** PASSED at export (2026-10-08 21:39:56 UTC). No rule errors, 1 warning(s), XSD check passed.

## 6. Milestones

- **Snapshot at upload** by ra.manager@beispiel-medizintechnik.de at 2026-10-08 21:38:27 UTC
- **Snapshot at export** by ra.manager@beispiel-medizintechnik.de at 2026-10-08 21:39:57 UTC

## 7. Full Timeline

- 2026-10-08 21:38:01 UTC. **File uploaded.** sample_catalogue.csv, 14 rows
- 2026-10-08 21:38:02 UTC. **Columns mapped.** 38 of 40 columns mapped (95%)
- 2026-10-08 21:38:03 UTC. **Validation at upload.** 1 error(s) for this device
- 2026-10-08 21:38:26 UTC. **Legislation determined.** MDR, stated in the uploaded file (FLD-UDID-11 as supplied (MDR))
- 2026-10-08 21:38:27 UTC. **Snapshot.** Snapshot at upload, by ra.manager@beispiel-medizintechnik.de
- 2026-10-08 21:38:28 UTC. **Device imported.** 38 fields imported, event #28
- 2026-10-08 21:38:29 UTC. **AI EMDN suggestion.** AI suggested P090804030201 (65% confidence)
- 2026-10-08 21:38:30 UTC. **Field change.** 2 field change(s) by the AI classifier, event #30
- 2026-10-08 21:39:11 UTC. **Field change.** 36 field change(s) by ra.manager@beispiel-medizintechnik.de, event #71
- 2026-10-08 21:39:30 UTC. **Field change.** 1 field change(s) by ra.manager@beispiel-medizintechnik.de, event #90
- 2026-10-08 21:39:31 UTC. **Field change.** 1 field change(s) by ra.manager@beispiel-medizintechnik.de, event #91
- 2026-10-08 21:39:56 UTC. **Validation at export.** 0 error(s), 1 warning(s). XSD check passed
- 2026-10-08 21:39:57 UTC. **Snapshot.** Snapshot at export, by ra.manager@beispiel-medizintechnik.de

# Device ART-1006, UDI-DI 04011616010068, "Zementfreier Hüftschaft Größe 6"

**Reference number:** ART-1006
**Device UDI-DI:** 04011616010068
**Name:** Zementfreier Hüftschaft Größe 6
**Legislation:** MDR, stated in the uploaded file
**Reviewed by:** ra.manager@beispiel-medizintechnik.de on 2026-10-08 21:39:33 UTC
**Events in this record:** 13

## 1. Data Provenance

- **sample_catalogue.csv** (csv, 14 rows), uploaded 2026-10-08 21:38:01 UTC

## 2. Column Mapping

- Mapped: 38 of 40 columns (95%)
- By method: exact match 33, normalised name 1, alias 0, AI 4
- Mandatory fields with no source column at upload: Nomenclature code (EMDN)

## 3. EMDN Classification

- **Confirmed by reviewer, the AI suggestion:** P090804010201 (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH FIXED NECK, STRAIGHT), AI confidence 90%
  - AI reasoning: Description states 'zementfrei' (uncemented) and 'Hüftschaft' (hip stem), so the code is supported. Neck type is not stated. A second check by another model could not be completed, so the first answer is shown.
  - Other codes listed for comparison. Their search match is not the confidence printed above. P090804010202 (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH FIXED NECK, ANATOMICAL) (search match 19%); P090804010206 (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH MODULAR NECK, STRAIGHT) (search match 65%); P090804010207 (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH MODULAR NECK, ANATOMICAL) (search match 65%); P090804030201 (REVISION UNCEMENTED FEMORAL STEMS, WITH FIXED NECK) (search match 62%)

## 3.5 Field-Level Reasoning

Each value below shows the source column, rule, reviewer action or AI rationale that produced it.

| Field | Value | Status | Source | Confidence | Reasoning |
|---|---|---|---|---|---|
| Device Name (FLD-UDID-22) | Zementfreier Hüftschaft Größe 6 | Approved | Exact column match, approved in a bulk review | 100% | Column "Bezeichnung" matched "Device Name" exactly. |
| Applicable Legislation (FLD-UDID-11) | MDR | Approved | Exact column match, approved in a bulk review | 100% | Column "Rechtsgrundlage" matched "Applicable Legislation" exactly. |

| Field | Value | Status | Source | Confidence | Reasoning |
|---|---|---|---|---|---|
| Risk Class (FLD-UDID-16) | Class III (CLASS_III) | Approved | Exact column match, approved in a bulk review | 100% | Column "Risikoklasse" matched "Risk Class" exactly. |
| Legal Manufacturer SRN (FLD-UDID-10) | DE-MF-000000042 | Approved | Exact column match, approved in a bulk review | 100% | Column "Hersteller-SRN" matched "Legal Manufacturer SRN" exactly. |
| Implantable (FLD-UDID-30) | true | Approved | Exact column match, approved in a bulk review | 100% | Column "Implantierbar" matched "Implantable" exactly. |
| Active Device (FLD-UDID-28) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Aktives Medizinprodukt" matched "Active Device" exactly. |
| Measuring Function (FLD-UDID-31) | false | Ready | Exact column match | 100% | Column "Messfunktion" matched "Measuring Function" exactly. |
| Reusable Surgical Instruments (FLD-UDID-32) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Wiederverwendbar" matched "Reusable Surgical Instruments" exactly. |
| Presence of animal tissues or cells (FLD-UDID-18) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Tierisches Gewebe" matched "Presence of animal tissues or cells" exactly. |
| Presence of human tissues or cells (FLD-UDID-23) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Menschliches Gewebe" matched "Presence of human tissues or cells" exactly. |
| Device intended to administer medicinal product (FLD-UDID-29) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Arzneimittelabgabe" matched "Device intended to administer medicinal product" exactly. |
| Substance - may be considered medicinal product (FLD-UDID-158) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Arzneimittel" matched "Substance - may be considered medicinal product" exactly. |
| Reference / Catalogue number (FLD-UDID-163) | ART-1006 | Approved | Exact column match, approved in a bulk review | 100% | Column "Artikelnummer" matched "Reference / Catalogue number" exactly. |
| Trade name (FLD-UDID-176) | DE: OrthoFlex Hip Stem Größe 6 | Approved | Exact column match, approved in a bulk review | 100% | Column "Handelsname" matched "Trade name" exactly. |
| UDI-DI code (FLD-UDID-178) | 04011616010068 | Approved | Exact column match, approved in a bulk review | 100% | Column "GTIN" matched "UDI-DI code" exactly. |
| Device labelled sterile (FLD-UDID-169) | true | Approved | Exact column match, approved in a bulk review | 100% | Column "Steril" matched "Device labelled sterile" exactly. |

| Field | Value | Status | Source | Confidence | Reasoning |
|---|---|---|---|---|---|
| Need for sterilisation before use (FLD-UDID-170) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Sterilisation" matched "Need for sterilisation before use" exactly. |
| Labelled as single use (FLD-UDID-167) | true | Approved | Exact column match, approved in a bulk review | 100% | Column "Einmalgebrauch" matched "Labelled as single use" exactly. |
| Reprocessed single use device (FLD-UDID-164) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Aufbereitet" matched "Reprocessed single use device" exactly. |
| Containing latex (FLD-UDID-156) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Enthält Latex" matched "Containing latex" exactly. |
| Device Status (FLD-UDID-130) | On the market (ON_THE_MARKET) | Approved | Exact column match, approved in a bulk review | 100% | Column "Marktstatus" matched "Device Status" exactly. |
| Type of UDI-PI (Production Identifier) (FLD-UDID-148) | Serialisation number (SERIALISATION_NUMBER) | Approved | Exact column match, approved in a bulk review | 100% | Column "UDI-PI Typ" matched "Type of UDI-PI (Production Identifier)" exactly. |
| Quantity of device (FLD-UDID-151) | 1 | Approved | Exact column match, approved in a bulk review | 100% | Column "Menge" matched "Quantity of device" exactly. |
| Certificate Type (FLD-UDID-60) | MDR type examination (MDR_TYPE_EXAMINATION) | Approved | Exact column match, approved in a bulk review | 100% | Column "Zertifikattyp" matched "Certificate Type" exactly. |
| Certificate Number (FLD-UDID-61) | 0123/2022/045678 | Approved | Exact column match, approved in a bulk review | 100% | Column "Zertifikatsnummer" matched "Certificate Number" exactly. |
| Notified Body (Certificate) (FLD-UDID-63) | 0123 | Approved | Exact column match, approved in a bulk review | 100% | Column "Benannte Stelle" matched "Notified Body (Certificate)" exactly. |
| Certificate Expiry Date (FLD-UDID-64) | 2027-04-30 | Approved | Exact column match, approved in a bulk review | 100% | Column "Ablaufdatum Zertifikat" matched "Certificate Expiry Date" exactly. |
| Member State where device is available (FLD-UDID-252) | DE,AT,FR,IT,ES,NL,BE,PL | Approved | Exact column match, approved in a bulk review | 100% | Column "Vertriebsland" matched "Member State where device is available" exactly. |
| Basic UDI-DI code (FLD-UDID-14) | 401161600010X5 | Approved | Column match after normalising the name, approved in a bulk review | 95% | Column "Basic-UDI-DI" matched "Basic UDI-DI code" after normalising punctuation/case. |
| Substance - human blood or plasma derived (FLD-UDID-155) | false | Approved | AI column mapping, approved in a bulk review | 95% | AI mapped column "Blut- oder Plasmaderivat" to "Substance - human blood or plasma derived" (confidence 0.95). German for human blood or plasma derived substance |

| Field | Value | Status | Source | Confidence | Reasoning |
|---|---|---|---|---|---|
| Market Info Start date (FLD-UDID-250) | 2023-06-15 | Approved | AI column mapping, approved in a bulk review | 90% | AI mapped column "Marktverfügbarkeit ab" to "Market Info Start date" (confidence 0.90). Complements mapped Member State availability |
| Issuing Entity Basic UDI-DI (FLD-UDID-01) | GS1 | Approved | Derived by rule, approved in a bulk review | 100% | Inferred from Basic UDI-DI code format, "401161600010X5" is a GS1 identifier. |
| Issuing Entity UDI-DI (FLD-UDID-291) | GS1 | Approved | Derived by rule, approved in a bulk review | 100% | Inferred from UDI-DI code format, "04011616010068" is a GS1 identifier. |
| System/Procedure Pack Type (FLD-UDID-12) | DEVICE | Approved | Declared by the customer, approved in a bulk review | 100% | Declared at project level by the project owner: every device in this project is a device in itself, not a system or a procedure pack (MDR Art. 22). EUDAMED field FLD-UDID-12. |
| Member State of first placing on EU market (FLD-UDID-137) | DE | Approved | Declared by the customer, approved in a bulk review | 100% | Declared at project level by the project owner: the devices in this project were first placed on the EU market in DE. EUDAMED field FLD-UDID-137. |
| Nomenclature code (EMDN) (FLD-UDID-149) | P090804010201 (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH FIXED NECK, STRAIGHT) | Approved | AI suggestion, approved by reviewer | 90% | Description states 'zementfrei' (uncemented) and 'Hüftschaft' (hip stem), so the code is supported. Neck type is not stated. A second check by another model could not be completed, so the first answer is shown. |
| Maximum number of reuses (FLD-UDID-157) | 0 | Approved | Derived by rule, approved by reviewer | 100% | Derived: device is labelled single use (FLD-UDID-167 = true), so maximum reuses is 0. |
| Sterilisation method (FLD-UDID-165) | ETO | Approved | Exact column match, approved in a bulk review | 100% | Column "Sterilisationsverfahren" matched "Sterilisation method" exactly. |

## 4. Human Overrides

No override by a reviewer was recorded. Section 4.1 lists every recorded change to this device, including approvals and other edits.

## 4.1 Change history

The device was imported at 2026-10-08 21:38:33 UTC with 38 fields (event #33). Each line is one recorded change, oldest first. The event number is its position in this project's audit trail.

**Nomenclature code (EMDN) (FLD-UDID-149)**

- 2026-10-08 21:38:35 UTC. The AI classifier, run by ra.manager@beispiel-medizintechnik.de, set a new suggestion. (empty) -> "P090804010201" (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH FIXED NECK, STRAIGHT). Event #35.
- 2026-10-08 21:39:32 UTC. ra.manager@beispiel-medizintechnik.de approved "P090804010201" (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH FIXED NECK, STRAIGHT). The AI had suggested "P090804010201" (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH FIXED NECK, STRAIGHT) with 90% confidence in event #34. Event #92.

**Maximum number of reuses (FLD-UDID-157)**

- 2026-10-08 21:38:35 UTC. The AI classifier, run by ra.manager@beispiel-medizintechnik.de, set a new suggestion. (empty) -> "0". Event #35.
- 2026-10-08 21:39:33 UTC. ra.manager@beispiel-medizintechnik.de approved "0". Event #93.

**Device Name (FLD-UDID-22)**

- 2026-10-08 21:39:12 UTC. ra.manager@beispiel-medizintechnik.de approved "Zementfreier Hüftschaft Größe 6" in bulk review B-07A2C765. Event #72.

**Applicable Legislation (FLD-UDID-11)**

- 2026-10-08 21:39:12 UTC. ra.manager@beispiel-medizintechnik.de approved "MDR" in bulk review B-07A2C765. Event #72.

**Risk Class (FLD-UDID-16)**

- 2026-10-08 21:39:12 UTC. ra.manager@beispiel-medizintechnik.de approved "CLASS_III" in bulk review B-07A2C765. Event #72.

**Legal Manufacturer SRN (FLD-UDID-10)**

- 2026-10-08 21:39:12 UTC. ra.manager@beispiel-medizintechnik.de approved "DE-MF-000000042" in bulk review B-07A2C765. Event #72.

**Implantable (FLD-UDID-30)**

- 2026-10-08 21:39:12 UTC. ra.manager@beispiel-medizintechnik.de approved "true" in bulk review B-07A2C765. Event #72.

**Active Device (FLD-UDID-28)**

- 2026-10-08 21:39:12 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #72.

**Measuring Function (FLD-UDID-31)**

- 2026-10-08 21:39:12 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #72.

**Reusable Surgical Instruments (FLD-UDID-32)**

- 2026-10-08 21:39:12 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #72.

**Presence of animal tissues or cells (FLD-UDID-18)**

- 2026-10-08 21:39:12 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #72.

**Presence of human tissues or cells (FLD-UDID-23)**

- 2026-10-08 21:39:12 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #72.

**Device intended to administer medicinal product (FLD-UDID-29)**

- 2026-10-08 21:39:12 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #72.

**Substance - may be considered medicinal product (FLD-UDID-158)**

- 2026-10-08 21:39:12 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #72.

**Reference / Catalogue number (FLD-UDID-163)**

- 2026-10-08 21:39:12 UTC. ra.manager@beispiel-medizintechnik.de approved "ART-1006" in bulk review B-07A2C765. Event #72.

**Trade name (FLD-UDID-176)**

- 2026-10-08 21:39:12 UTC. ra.manager@beispiel-medizintechnik.de approved "DE: OrthoFlex Hip Stem Größe 6" in bulk review B-07A2C765. Event #72.

**UDI-DI code (FLD-UDID-178)**

- 2026-10-08 21:39:12 UTC. ra.manager@beispiel-medizintechnik.de approved "04011616010068" in bulk review B-07A2C765. Event #72.

**Device labelled sterile (FLD-UDID-169)**

- 2026-10-08 21:39:12 UTC. ra.manager@beispiel-medizintechnik.de approved "true" in bulk review B-07A2C765. Event #72.

**Need for sterilisation before use (FLD-UDID-170)**

- 2026-10-08 21:39:12 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #72.

**Labelled as single use (FLD-UDID-167)**

- 2026-10-08 21:39:12 UTC. ra.manager@beispiel-medizintechnik.de approved "true" in bulk review B-07A2C765. Event #72.

**Reprocessed single use device (FLD-UDID-164)**

- 2026-10-08 21:39:12 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #72.

**Containing latex (FLD-UDID-156)**

- 2026-10-08 21:39:12 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #72.

**Device Status (FLD-UDID-130)**

- 2026-10-08 21:39:12 UTC. ra.manager@beispiel-medizintechnik.de approved "ON_THE_MARKET" in bulk review B-07A2C765. Event #72.

**Type of UDI-PI (Production Identifier) (FLD-UDID-148)**

- 2026-10-08 21:39:12 UTC. ra.manager@beispiel-medizintechnik.de approved "SERIALISATION_NUMBER" in bulk review B-07A2C765. Event #72.

**Quantity of device (FLD-UDID-151)**

- 2026-10-08 21:39:12 UTC. ra.manager@beispiel-medizintechnik.de approved "1" in bulk review B-07A2C765. Event #72.

**Certificate Type (FLD-UDID-60)**

- 2026-10-08 21:39:12 UTC. ra.manager@beispiel-medizintechnik.de approved "MDR_TYPE_EXAMINATION" in bulk review B-07A2C765. Event #72.

**Certificate Number (FLD-UDID-61)**

- 2026-10-08 21:39:12 UTC. ra.manager@beispiel-medizintechnik.de approved "0123/2022/045678" in bulk review B-07A2C765. Event #72.

**Notified Body (Certificate) (FLD-UDID-63)**

- 2026-10-08 21:39:12 UTC. ra.manager@beispiel-medizintechnik.de approved "0123" in bulk review B-07A2C765. Event #72.

**Certificate Expiry Date (FLD-UDID-64)**

- 2026-10-08 21:39:12 UTC. ra.manager@beispiel-medizintechnik.de approved "2027-04-30" in bulk review B-07A2C765. Event #72.

**Member State where device is available (FLD-UDID-252)**

- 2026-10-08 21:39:12 UTC. ra.manager@beispiel-medizintechnik.de approved "DE,AT,FR,IT,ES,NL,BE,PL" in bulk review B-07A2C765. Event #72.

**Basic UDI-DI code (FLD-UDID-14)**

- 2026-10-08 21:39:12 UTC. ra.manager@beispiel-medizintechnik.de approved "401161600010X5" in bulk review B-07A2C765. Event #72.

**Substance - human blood or plasma derived (FLD-UDID-155)**

- 2026-10-08 21:39:12 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #72.

**Market Info Start date (FLD-UDID-250)**

- 2026-10-08 21:39:12 UTC. ra.manager@beispiel-medizintechnik.de approved "2023-06-15" in bulk review B-07A2C765. Event #72.

**Issuing Entity Basic UDI-DI (FLD-UDID-01)**

- 2026-10-08 21:39:12 UTC. ra.manager@beispiel-medizintechnik.de approved "GS1" in bulk review B-07A2C765. Event #72.

**Issuing Entity UDI-DI (FLD-UDID-291)**

- 2026-10-08 21:39:12 UTC. ra.manager@beispiel-medizintechnik.de approved "GS1" in bulk review B-07A2C765. Event #72.

**System/Procedure Pack Type (FLD-UDID-12)**

- 2026-10-08 21:39:12 UTC. ra.manager@beispiel-medizintechnik.de approved "DEVICE" in bulk review B-07A2C765. Event #72.

**Member State of first placing on EU market (FLD-UDID-137)**

- 2026-10-08 21:39:12 UTC. ra.manager@beispiel-medizintechnik.de approved "DE" in bulk review B-07A2C765. Event #72.

**Sterilisation method (FLD-UDID-165)**

- 2026-10-08 21:39:12 UTC. ra.manager@beispiel-medizintechnik.de approved "ETO" in bulk review B-07A2C765. Event #72.

## 5. Validation History

- At upload, 2026-10-08 21:38:03 UTC. The rule check found 1 error(s) for this device
  - Error BR-MANDATORY, FLD-UDID-149. The rule check reported "Mandatory field missing for MDR".
- At export, 2026-10-08 21:39:58 UTC. 0 error(s), 0 warning(s) for this device under MDR
  - Language of a text. Trade name (FLD-UDID-176) is DE. The language code was written before the text in the uploaded file.
  - Passed EUDAMED's XSD format check.
- **Final status:** PASSED at export (2026-10-08 21:39:58 UTC). No rule errors, 0 warning(s), XSD check passed.

## 6. Milestones

- **Snapshot at upload** by ra.manager@beispiel-medizintechnik.de at 2026-10-08 21:38:32 UTC
- **Snapshot at export** by ra.manager@beispiel-medizintechnik.de at 2026-10-08 21:39:59 UTC

## 7. Full Timeline

- 2026-10-08 21:38:01 UTC. **File uploaded.** sample_catalogue.csv, 14 rows
- 2026-10-08 21:38:02 UTC. **Columns mapped.** 38 of 40 columns mapped (95%)
- 2026-10-08 21:38:03 UTC. **Validation at upload.** 1 error(s) for this device
- 2026-10-08 21:38:31 UTC. **Legislation determined.** MDR, stated in the uploaded file (FLD-UDID-11 as supplied (MDR))
- 2026-10-08 21:38:32 UTC. **Snapshot.** Snapshot at upload, by ra.manager@beispiel-medizintechnik.de
- 2026-10-08 21:38:33 UTC. **Device imported.** 38 fields imported, event #33

- 2026-10-08 21:38:34 UTC. **AI EMDN suggestion.** AI suggested P090804010201 (90% confidence)
- 2026-10-08 21:38:35 UTC. **Field change.** 2 field change(s) by the AI classifier, event #35
- 2026-10-08 21:39:12 UTC. **Field change.** 36 field change(s) by ra.manager@beispiel-medizintechnik.de, event #72
- 2026-10-08 21:39:32 UTC. **Field change.** 1 field change(s) by ra.manager@beispiel-medizintechnik.de, event #92
- 2026-10-08 21:39:33 UTC. **Field change.** 1 field change(s) by ra.manager@beispiel-medizintechnik.de, event #93
- 2026-10-08 21:39:58 UTC. **Validation at export.** 0 error(s), 0 warning(s). XSD check passed
- 2026-10-08 21:39:59 UTC. **Snapshot.** Snapshot at export, by ra.manager@beispiel-medizintechnik.de

# Device ART-1007, UDI-DI 04011616010075, "Zementfreier Hüftschaft Größe 7"

**Reference number:** ART-1007
**Device UDI-DI:** 04011616010075
**Name:** Zementfreier Hüftschaft Größe 7
**Legislation:** MDR, stated in the uploaded file
**Reviewed by:** ra.manager@beispiel-medizintechnik.de on 2026-10-08 21:39:35 UTC
**Events in this record:** 13

## 1. Data Provenance

- **sample_catalogue.csv** (csv, 14 rows), uploaded 2026-10-08 21:38:01 UTC

## 2. Column Mapping

- Mapped: 38 of 40 columns (95%)
- By method: exact match 33, normalised name 1, alias 0, AI 4
- Mandatory fields with no source column at upload: Nomenclature code (EMDN)

## 3. EMDN Classification

- **Confirmed by reviewer, the AI suggestion:** P090804010202 (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH FIXED NECK, ANATOMICAL), AI confidence 90%
  - AI reasoning: Description states 'zementfrei' (uncemented) and 'Hüftschaft' (hip stem), so the code is supported. Neck type is not stated. A second check by another model could not be completed, so the first answer is shown.
  - Other codes listed for comparison. Their search match is not the confidence printed above. P090804010201 (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH FIXED NECK, STRAIGHT) (search match 19%); P090804010206 (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH MODULAR NECK, STRAIGHT) (search match 65%); P090804010207 (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH MODULAR NECK, ANATOMICAL) (search match 65%); P090804030201 (REVISION UNCEMENTED FEMORAL STEMS, WITH FIXED NECK) (search match 62%)

## 3.5 Field-Level Reasoning

Each value below shows the source column, rule, reviewer action or AI rationale that produced it.

| Field | Value | Status | Source | Confidence | Reasoning |
|---|---|---|---|---|---|
| Device Name (FLD-UDID-22) | Zementfreier Hüftschaft Größe 7 | Approved | Exact column match, approved in a bulk review | 100% | Column "Bezeichnung" matched "Device Name" exactly. |
| Applicable Legislation (FLD-UDID-11) | MDR | Approved | Exact column match, approved in a bulk review | 100% | Column "Rechtsgrundlage" matched "Applicable Legislation" exactly. |

| Field | Value | Status | Source | Confidence | Reasoning |
|---|---|---|---|---|---|
| Risk Class (FLD-UDID-16) | Class III (CLASS_III) | Approved | Exact column match, approved in a bulk review | 100% | Column "Risikoklasse" matched "Risk Class" exactly. |
| Legal Manufacturer SRN (FLD-UDID-10) | DE-MF-000000042 | Approved | Exact column match, approved in a bulk review | 100% | Column "Hersteller-SRN" matched "Legal Manufacturer SRN" exactly. |
| Implantable (FLD-UDID-30) | true | Approved | Exact column match, approved in a bulk review | 100% | Column "Implantierbar" matched "Implantable" exactly. |
| Active Device (FLD-UDID-28) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Aktives Medizinprodukt" matched "Active Device" exactly. |
| Measuring Function (FLD-UDID-31) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Messfunktion" matched "Measuring Function" exactly. |
| Reusable Surgical Instruments (FLD-UDID-32) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Wiederverwendbar" matched "Reusable Surgical Instruments" exactly. |
| Presence of animal tissues or cells (FLD-UDID-18) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Tierisches Gewebe" matched "Presence of animal tissues or cells" exactly. |
| Presence of human tissues or cells (FLD-UDID-23) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Menschliches Gewebe" matched "Presence of human tissues or cells" exactly. |
| Device intended to administer medicinal product (FLD-UDID-29) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Arzneimittelabgabe" matched "Device intended to administer medicinal product" exactly. |
| Substance - may be considered medicinal product (FLD-UDID-158) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Arzneimittel" matched "Substance - may be considered medicinal product" exactly. |
| Reference / Catalogue number (FLD-UDID-163) | ART-1007 | Approved | Exact column match, approved in a bulk review | 100% | Column "Artikelnummer" matched "Reference / Catalogue number" exactly. |
| Trade name (FLD-UDID-176) | DE: OrthoFlex Hip Stem Größe 7 | Approved | Exact column match, approved in a bulk review | 100% | Column "Handelsname" matched "Trade name" exactly. |
| UDI-DI code (FLD-UDID-178) | 04011616010075 | Approved | Exact column match, approved in a bulk review | 100% | Column "GTIN" matched "UDI-DI code" exactly. |
| Device labelled sterile (FLD-UDID-169) | true | Approved | Exact column match, approved in a bulk review | 100% | Column "Steril" matched "Device labelled sterile" exactly. |

| Field | Value | Status | Source | Confidence | Reasoning |
|---|---|---|---|---|---|
| Need for sterilisation before use (FLD-UDID-170) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Sterilisation" matched "Need for sterilisation before use" exactly. |
| Labelled as single use (FLD-UDID-167) | true | Approved | Exact column match, approved in a bulk review | 100% | Column "Einmalgebrauch" matched "Labelled as single use" exactly. |
| Reprocessed single use device (FLD-UDID-164) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Aufbereitet" matched "Reprocessed single use device" exactly. |
| Containing latex (FLD-UDID-156) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Enthält Latex" matched "Containing latex" exactly. |
| Device Status (FLD-UDID-130) | On the market (ON_THE_MARKET) | Approved | Exact column match, approved in a bulk review | 100% | Column "Marktstatus" matched "Device Status" exactly. |
| Type of UDI-PI (Production Identifier) (FLD-UDID-148) | Serialisation number (SERIALISATION_NUMBER) | Approved | Exact column match, approved in a bulk review | 100% | Column "UDI-PI Typ" matched "Type of UDI-PI (Production Identifier)" exactly. |
| Quantity of device (FLD-UDID-151) | 1 | Approved | Exact column match, approved in a bulk review | 100% | Column "Menge" matched "Quantity of device" exactly. |
| Certificate Type (FLD-UDID-60) | MDR type examination (MDR_TYPE_EXAMINATION) | Approved | Exact column match, approved in a bulk review | 100% | Column "Zertifikattyp" matched "Certificate Type" exactly. |
| Certificate Number (FLD-UDID-61) | 0123/2022/045678 | Approved | Exact column match, approved in a bulk review | 100% | Column "Zertifikatsnummer" matched "Certificate Number" exactly. |
| Notified Body (Certificate) (FLD-UDID-63) | 0123 | Approved | Exact column match, approved in a bulk review | 100% | Column "Benannte Stelle" matched "Notified Body (Certificate)" exactly. |
| Certificate Expiry Date (FLD-UDID-64) | 2027-04-30 | Approved | Exact column match, approved in a bulk review | 100% | Column "Ablaufdatum Zertifikat" matched "Certificate Expiry Date" exactly. |
| Member State where device is available (FLD-UDID-252) | DE,AT,FR,IT,ES,NL,BE,PL | Approved | Exact column match, approved in a bulk review | 100% | Column "Vertriebsland" matched "Member State where device is available" exactly. |
| Basic UDI-DI code (FLD-UDID-14) | 401161600010X5 | Approved | Column match after normalising the name, approved in a bulk review | 95% | Column "Basic-UDI-DI" matched "Basic UDI-DI code" after normalising punctuation/case. |
| Substance - human blood or plasma derived (FLD-UDID-155) | false | Approved | AI column mapping, approved in a bulk review | 95% | AI mapped column "Blut- oder Plasmaderivat" to "Substance - human blood or plasma derived" (confidence 0.95). German for human blood or plasma derived substance |

| Field | Value | Status | Source | Confidence | Reasoning |
|---|---|---|---|---|---|
| Market Info Start date (FLD-UDID-250) | 2023-06-15 | Approved | AI column mapping, approved in a bulk review | 90% | AI mapped column "Marktverfügbarkeit ab" to "Market Info Start date" (confidence 0.90). Complements mapped Member State availability |
| Issuing Entity Basic UDI-DI (FLD-UDID-01) | GS1 | Approved | Derived by rule, approved in a bulk review | 100% | Inferred from Basic UDI-DI code format, "401161600010X5" is a GS1 identifier. |
| Issuing Entity UDI-DI (FLD-UDID-291) | GS1 | Approved | Derived by rule, approved in a bulk review | 100% | Inferred from UDI-DI code format, "04011616010075" is a GS1 identifier. |
| System/Procedure Pack Type (FLD-UDID-12) | DEVICE | Approved | Declared by the customer, approved in a bulk review | 100% | Declared at project level by the project owner: every device in this project is a device in itself, not a system or a procedure pack (MDR Art. 22). EUDAMED field FLD-UDID-12. |
| Member State of first placing on EU market (FLD-UDID-137) | DE | Approved | Declared by the customer, approved in a bulk review | 100% | Declared at project level by the project owner: the devices in this project were first placed on the EU market in DE. EUDAMED field FLD-UDID-137. |
| Nomenclature code (EMDN) (FLD-UDID-149) | P090804010202 (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH FIXED NECK, ANATOMICAL) | Approved | AI suggestion, approved by reviewer | 90% | Description states 'zementfrei' (uncemented) and 'Hüftschaft' (hip stem), so the code is supported. Neck type is not stated. A second check by another model could not be completed, so the first answer is shown. |
| Maximum number of reuses (FLD-UDID-157) | 0 | Approved | Derived by rule, approved by reviewer | 100% | Derived: device is labelled single use (FLD-UDID-167 = true), so maximum reuses is 0. |
| Sterilisation method (FLD-UDID-165) | ETO | Approved | Exact column match, approved in a bulk review | 100% | Column "Sterilisationsverfahren" matched "Sterilisation method" exactly. |

## 4. Human Overrides

No override by a reviewer was recorded. Section 4.1 lists every recorded change to this device, including approvals and other edits.

## 4.1 Change history

The device was imported at 2026-10-08 21:38:38 UTC with 38 fields (event #38). Each line is one recorded change, oldest first. The event number is its position in this project's audit trail.

**Nomenclature code (EMDN) (FLD-UDID-149)**

- 2026-10-08 21:38:40 UTC. The AI classifier, run by ra.manager@beispiel-medizintechnik.de, set a new suggestion. (empty) -> "P090804010202" (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH FIXED NECK, ANATOMICAL). Event #40.
- 2026-10-08 21:39:34 UTC. ra.manager@beispiel-medizintechnik.de approved "P090804010202" (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH FIXED NECK, ANATOMICAL). The AI had suggested "P090804010202" (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH FIXED NECK, ANATOMICAL) with 90% confidence in event #39. Event #94.

**Maximum number of reuses (FLD-UDID-157)**

- 2026-10-08 21:38:40 UTC. The AI classifier, run by ra.manager@beispiel-medizintechnik.de, set a new suggestion. (empty) -> "0". Event #40.
- 2026-10-08 21:39:35 UTC. ra.manager@beispiel-medizintechnik.de approved "0". Event #95.

**Device Name (FLD-UDID-22)**

- 2026-10-08 21:39:13 UTC. ra.manager@beispiel-medizintechnik.de approved "Zementfreier Hüftschaft Größe 7" in bulk review B-07A2C765. Event #73.

**Applicable Legislation (FLD-UDID-11)**

- 2026-10-08 21:39:13 UTC. ra.manager@beispiel-medizintechnik.de approved "MDR" in bulk review B-07A2C765. Event #73.

**Risk Class (FLD-UDID-16)**

- 2026-10-08 21:39:13 UTC. ra.manager@beispiel-medizintechnik.de approved "CLASS_III" in bulk review B-07A2C765. Event #73.

**Legal Manufacturer SRN (FLD-UDID-10)**

- 2026-10-08 21:39:13 UTC. ra.manager@beispiel-medizintechnik.de approved "DE-MF-000000042" in bulk review B-07A2C765. Event #73.

**Implantable (FLD-UDID-30)**

- 2026-10-08 21:39:13 UTC. ra.manager@beispiel-medizintechnik.de approved "true" in bulk review B-07A2C765. Event #73.

**Active Device (FLD-UDID-28)**

- 2026-10-08 21:39:13 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #73.

**Measuring Function (FLD-UDID-31)**

- 2026-10-08 21:39:13 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #73.

**Reusable Surgical Instruments (FLD-UDID-32)**

- 2026-10-08 21:39:13 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #73.

**Presence of animal tissues or cells (FLD-UDID-18)**

- 2026-10-08 21:39:13 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #73.

**Presence of human tissues or cells (FLD-UDID-23)**

- 2026-10-08 21:39:13 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #73.

**Device intended to administer medicinal product (FLD-UDID-29)**

- 2026-10-08 21:39:13 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #73.

**Substance - may be considered medicinal product (FLD-UDID-158)**

- 2026-10-08 21:39:13 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #73.

**Reference / Catalogue number (FLD-UDID-163)**

- 2026-10-08 21:39:13 UTC. ra.manager@beispiel-medizintechnik.de approved "ART-1007" in bulk review B-07A2C765. Event #73.

**Trade name (FLD-UDID-176)**

- 2026-10-08 21:39:13 UTC. ra.manager@beispiel-medizintechnik.de approved "DE: OrthoFlex Hip Stem Größe 7" in bulk review B-07A2C765. Event #73.

**UDI-DI code (FLD-UDID-178)**

- 2026-10-08 21:39:13 UTC. ra.manager@beispiel-medizintechnik.de approved "04011616010075" in bulk review B-07A2C765. Event #73.

**Device labelled sterile (FLD-UDID-169)**

- 2026-10-08 21:39:13 UTC. ra.manager@beispiel-medizintechnik.de approved "true" in bulk review B-07A2C765. Event #73.

**Need for sterilisation before use (FLD-UDID-170)**

- 2026-10-08 21:39:13 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #73.

**Labelled as single use (FLD-UDID-167)**

- 2026-10-08 21:39:13 UTC. ra.manager@beispiel-medizintechnik.de approved "true" in bulk review B-07A2C765. Event #73.

**Reprocessed single use device (FLD-UDID-164)**

- 2026-10-08 21:39:13 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #73.

**Containing latex (FLD-UDID-156)**

- 2026-10-08 21:39:13 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #73.

**Device Status (FLD-UDID-130)**

- 2026-10-08 21:39:13 UTC. ra.manager@beispiel-medizintechnik.de approved "ON_THE_MARKET" in bulk review B-07A2C765. Event #73.

**Type of UDI-PI (Production Identifier) (FLD-UDID-148)**

- 2026-10-08 21:39:13 UTC. ra.manager@beispiel-medizintechnik.de approved "SERIALISATION_NUMBER" in bulk review B-07A2C765. Event #73.

**Quantity of device (FLD-UDID-151)**

- 2026-10-08 21:39:13 UTC. ra.manager@beispiel-medizintechnik.de approved "1" in bulk review B-07A2C765. Event #73.

**Certificate Type (FLD-UDID-60)**

- 2026-10-08 21:39:13 UTC. ra.manager@beispiel-medizintechnik.de approved "MDR_TYPE_EXAMINATION" in bulk review B-07A2C765. Event #73.

**Certificate Number (FLD-UDID-61)**

- 2026-10-08 21:39:13 UTC. ra.manager@beispiel-medizintechnik.de approved "0123/2022/045678" in bulk review B-07A2C765. Event #73.

**Notified Body (Certificate) (FLD-UDID-63)**

- 2026-10-08 21:39:13 UTC. ra.manager@beispiel-medizintechnik.de approved "0123" in bulk review B-07A2C765. Event #73.

**Certificate Expiry Date (FLD-UDID-64)**

- 2026-10-08 21:39:13 UTC. ra.manager@beispiel-medizintechnik.de approved "2027-04-30" in bulk review B-07A2C765. Event #73.

**Member State where device is available (FLD-UDID-252)**

- 2026-10-08 21:39:13 UTC. ra.manager@beispiel-medizintechnik.de approved "DE,AT,FR,IT,ES,NL,BE,PL" in bulk review B-07A2C765. Event #73.

**Basic UDI-DI code (FLD-UDID-14)**

- 2026-10-08 21:39:13 UTC. ra.manager@beispiel-medizintechnik.de approved "401161600010X5" in bulk review B-07A2C765. Event #73.

**Substance - human blood or plasma derived (FLD-UDID-155)**

- 2026-10-08 21:39:13 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #73.

**Market Info Start date (FLD-UDID-250)**

- 2026-10-08 21:39:13 UTC. ra.manager@beispiel-medizintechnik.de approved "2023-06-15" in bulk review B-07A2C765. Event #73.

**Issuing Entity Basic UDI-DI (FLD-UDID-01)**

- 2026-10-08 21:39:13 UTC. ra.manager@beispiel-medizintechnik.de approved "GS1" in bulk review B-07A2C765. Event #73.

**Issuing Entity UDI-DI (FLD-UDID-291)**

- 2026-10-08 21:39:13 UTC. ra.manager@beispiel-medizintechnik.de approved "GS1" in bulk review B-07A2C765. Event #73.

**System/Procedure Pack Type (FLD-UDID-12)**

- 2026-10-08 21:39:13 UTC. ra.manager@beispiel-medizintechnik.de approved "DEVICE" in bulk review B-07A2C765. Event #73.

**Member State of first placing on EU market (FLD-UDID-137)**

- 2026-10-08 21:39:13 UTC. ra.manager@beispiel-medizintechnik.de approved "DE" in bulk review B-07A2C765. Event #73.

**Sterilisation method (FLD-UDID-165)**

- 2026-10-08 21:39:13 UTC. ra.manager@beispiel-medizintechnik.de approved "ETO" in bulk review B-07A2C765. Event #73.

## 5. Validation History

- At upload, 2026-10-08 21:38:03 UTC. The rule check found 1 error(s) for this device
  - Error BR-MANDATORY, FLD-UDID-149. The rule check reported "Mandatory field missing for MDR".
- At export, 2026-10-08 21:40:00 UTC. 1 error(s), 0 warning(s) for this device under MDR
  - Error BR-CONSISTENCY, FLD-UDID-64. The rule check reported "Certificate expires before the market start date".
  - Language of a text. Trade name (FLD-UDID-176) is DE. The language code was written before the text in the uploaded file.
  - Passed EUDAMED's XSD format check.
- **Final status:** NOT PASSED at export (2026-10-08 21:40:00 UTC). 1 rule error(s) remain, 0 warning(s), XSD check passed. Rule errors remained on this device at export. ra.manager@beispiel-medizintechnik.de confirmed the export anyway.

## 6. Milestones

- **Snapshot at upload** by ra.manager@beispiel-medizintechnik.de at 2026-10-08 21:38:37 UTC
- **Snapshot at export** by ra.manager@beispiel-medizintechnik.de at 2026-10-08 21:40:01 UTC

## 7. Full Timeline

- 2026-10-08 21:38:01 UTC. **File uploaded.** sample_catalogue.csv, 14 rows
- 2026-10-08 21:38:02 UTC. **Columns mapped.** 38 of 40 columns mapped (95%)
- 2026-10-08 21:38:03 UTC. **Validation at upload.** 1 error(s) for this device

- 2026-10-08 21:38:36 UTC. **Legislation determined.** MDR, stated in the uploaded file (FLD-UDID-11 as supplied (MDR))
- 2026-10-08 21:38:37 UTC. **Snapshot.** Snapshot at upload, by ra.manager@beispiel-medizintechnik.de
- 2026-10-08 21:38:38 UTC. **Device imported.** 38 fields imported, event #38
- 2026-10-08 21:38:39 UTC. **AI EMDN suggestion.** AI suggested P090804010202 (90% confidence)
- 2026-10-08 21:38:40 UTC. **Field change.** 2 field change(s) by the AI classifier, event #40
- 2026-10-08 21:39:13 UTC. **Field change.** 36 field change(s) by ra.manager@beispiel-medizintechnik.de, event #73
- 2026-10-08 21:39:34 UTC. **Field change.** 1 field change(s) by ra.manager@beispiel-medizintechnik.de, event #94
- 2026-10-08 21:39:35 UTC. **Field change.** 1 field change(s) by ra.manager@beispiel-medizintechnik.de, event #95
- 2026-10-08 21:40:00 UTC. **Validation at export.** 1 error(s), 0 warning(s). XSD check passed
- 2026-10-08 21:40:01 UTC. **Snapshot.** Snapshot at export, by ra.manager@beispiel-medizintechnik.de

# Device ART-1008, UDI-DI 04011616010082, "Zementfreier Hüftschaft Größe 8"

**Reference number:** ART-1008
**Device UDI-DI:** 04011616010082
**Name:** Zementfreier Hüftschaft Größe 8
**Legislation:** MDR, stated in the uploaded file
**Reviewed by:** ra.manager@beispiel-medizintechnik.de on 2026-10-08 21:39:37 UTC
**Events in this record:** 13

## 1. Data Provenance

- **sample_catalogue.csv** (csv, 14 rows), uploaded 2026-10-08 21:38:01 UTC

## 2. Column Mapping

- Mapped: 38 of 40 columns (95%)
- By method: exact match 33, normalised name 1, alias 0, AI 4
- Mandatory fields with no source column at upload: Nomenclature code (EMDN)

## 3. EMDN Classification

- **Confirmed by reviewer, the AI suggestion:** P090804010206 (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH MODULAR NECK, STRAIGHT), AI confidence 65%
  - AI reasoning: The description's own words did not point to P090804010206. Similar devices registered in EUDAMED use this code (5 manufacturers, 334 registrations, 22% of filings, registered name similar in meaning to "quill pdo quill pdo polydioxanone"). Same product family, USP 3-0. A second check by another model could not be completed, so the first answer is shown.
  - Other codes listed for comparison. Their search match is not the confidence printed above. P090804010201 (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH FIXED NECK, STRAIGHT) (search match 19%); P090804010202 (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH FIXED NECK, ANATOMICAL) (search match 65%); P090804010207 (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH MODULAR NECK, ANATOMICAL) (search match 65%); P090804030201 (REVISION UNCEMENTED FEMORAL STEMS, WITH FIXED NECK) (search match 62%)

## 3.5 Field-Level Reasoning

Each value below shows the source column, rule, reviewer action or AI rationale that produced it.

| Field | Value | Status | Source | Confidence | Reasoning |
|---|---|---|---|---|---|
| Device Name (FLD-UDID-22) | Zementfreier Hüftschaft Größe 8 | Approved | Exact column match, approved in a bulk review | 100% | Column "Bezeichnung" matched "Device Name" exactly. |
| Applicable Legislation (FLD-UDID-11) | MDR | Approved | Exact column match, approved in a bulk review | 100% | Column "Rechtsgrundlage" matched "Applicable Legislation" exactly. |
| Risk Class (FLD-UDID-16) | Class III (CLASS_III) | Approved | Exact column match, approved in a bulk review | 100% | Column "Risikoklasse" matched "Risk Class" exactly. |
| Legal Manufacturer SRN (FLD-UDID-10) | DE-MF-000000042 | Approved | Exact column match, approved in a bulk review | 100% | Column "Hersteller-SRN" matched "Legal Manufacturer SRN" exactly. |
| Implantable (FLD-UDID-30) | true | Approved | Exact column match, approved in a bulk review | 100% | Column "Implantierbar" matched "Implantable" exactly. |
| Active Device (FLD-UDID-28) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Aktives Medizinprodukt" matched "Active Device" exactly. |
| Measuring Function (FLD-UDID-31) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Messfunktion" matched "Measuring Function" exactly. |
| Reusable Surgical Instruments (FLD-UDID-32) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Wiederverwendbar" matched "Reusable Surgical Instruments" exactly. |
| Presence of animal tissues or cells (FLD-UDID-18) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Tierisches Gewebe" matched "Presence of animal tissues or cells" exactly. |
| Presence of human tissues or cells (FLD-UDID-23) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Menschliches Gewebe" matched "Presence of human tissues or cells" exactly. |
| Device intended to administer medicinal product (FLD-UDID-29) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Arzneimittelabgabe" matched "Device intended to administer medicinal product" exactly. |
| Substance - may be considered medicinal product (FLD-UDID-158) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Arzneimittel" matched "Substance - may be considered medicinal product" exactly. |
| Reference / Catalogue number (FLD-UDID-163) | ART-1008 | Approved | Exact column match, approved in a bulk review | 100% | Column "Artikelnummer" matched "Reference / Catalogue number" exactly. |

| Field | Value | Status | Source | Confidence | Reasoning |
|---|---|---|---|---|---|
| Trade name (FLD-UDID-176) | DE: OrthoFlex Hip Stem Größe 8 | Approved | Exact column match, approved in a bulk review | 100% | Column "Handelsname" matched "Trade name" exactly. |
| UDI-DI code (FLD-UDID-178) | 04011616010082 | Approved | Exact column match, approved in a bulk review | 100% | Column "GTIN" matched "UDI-DI code" exactly. |
| Device labelled sterile (FLD-UDID-169) | true | Approved | Exact column match, approved in a bulk review | 100% | Column "Steril" matched "Device labelled sterile" exactly. |
| Need for sterilisation before use (FLD-UDID-170) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Sterilisation" matched "Need for sterilisation before use" exactly. |
| Labelled as single use (FLD-UDID-167) | true | Approved | Exact column match, approved in a bulk review | 100% | Column "Einmalgebrauch" matched "Labelled as single use" exactly. |
| Reprocessed single use device (FLD-UDID-164) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Aufbereitet" matched "Reprocessed single use device" exactly. |
| Containing latex (FLD-UDID-156) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Enthält Latex" matched "Containing latex" exactly. |
| Device Status (FLD-UDID-130) | On the market (ON_THE_MARKET) | Approved | Exact column match, approved in a bulk review | 100% | Column "Marktstatus" matched "Device Status" exactly. |
| Type of UDI-PI (Production Identifier) (FLD-UDID-148) | Serialisation number (SERIALISATION_NUMBER) | Approved | Exact column match, approved in a bulk review | 100% | Column "UDI-PI Typ" matched "Type of UDI-PI (Production Identifier)" exactly. |
| Quantity of device (FLD-UDID-151) | 1 | Approved | Exact column match, approved in a bulk review | 100% | Column "Menge" matched "Quantity of device" exactly. |
| Certificate Type (FLD-UDID-60) | MDR type examination (MDR_TYPE_EXAMINATION) | Approved | Exact column match, approved in a bulk review | 100% | Column "Zertifikattyp" matched "Certificate Type" exactly. |
| Certificate Number (FLD-UDID-61) | 0123/2022/045678 | Approved | Exact column match, approved in a bulk review | 100% | Column "Zertifikatsnummer" matched "Certificate Number" exactly. |
| Notified Body (Certificate) (FLD-UDID-63) | 0123 | Approved | Exact column match, approved in a bulk review | 100% | Column "Benannte Stelle" matched "Notified Body (Certificate)" exactly. |
| Certificate Expiry Date (FLD-UDID-64) | 2027-04-30 | Approved | Exact column match, approved in a bulk review | 100% | Column "Ablaufdatum Zertifikat" matched "Certificate Expiry Date" exactly. |
| Member State where device is available (FLD-UDID-252) | DE,AT,FR,IT,ES,NL,BE,PL | Approved | Exact column match, approved in a bulk review | 100% | Column "Vertriebsland" matched "Member State where device is available" exactly. |
| Basic UDI-DI code (FLD-UDID-14) | 401161600010X5 | Approved | Column match after normalising the name, approved in a bulk review | 95% | Column "Basic-UDI-DI" matched "Basic UDI-DI code" after normalising punctuation/case. |

| Field | Value | Status | Source | Confidence | Reasoning |
|---|---|---|---|---|---|
| Substance - human blood or plasma derived (FLD-UDID-155) | false | Approved | AI column mapping, approved in a bulk review | 95% | AI mapped column "Blut- oder Plasmaderivat" to "Substance - human blood or plasma derived" (confidence 0.95). German for human blood or plasma derived substance |
| Market Info Start date (FLD-UDID-250) | 2023-06-15 | Approved | AI column mapping, approved in a bulk review | 90% | AI mapped column "Marktverfügbarkeit ab" to "Market Info Start date" (confidence 0.90). Complements mapped Member State availability |
| Issuing Entity Basic UDI-DI (FLD-UDID-01) | GS1 | Approved | Derived by rule, approved in a bulk review | 100% | Inferred from Basic UDI-DI code format, "401161600010X5" is a GS1 identifier. |
| Issuing Entity UDI-DI (FLD-UDID-291) | GS1 | Approved | Derived by rule, approved in a bulk review | 100% | Inferred from UDI-DI code format, "04011616010082" is a GS1 identifier. |
| System/Procedure Pack Type (FLD-UDID-12) | DEVICE | Approved | Declared by the customer, approved in a bulk review | 100% | Declared at project level by the project owner: every device in this project is a device in itself, not a system or a procedure pack (MDR Art. 22). EUDAMED field FLD-UDID-12. |
| Member State of first placing on EU market (FLD-UDID-137) | DE | Approved | Declared by the customer, approved in a bulk review | 100% | Declared at project level by the project owner: the devices in this project were first placed on the EU market in DE. EUDAMED field FLD-UDID-137. |
| Nomenclature code (EMDN) (FLD-UDID-149) | P090804010206 (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH MODULAR NECK, STRAIGHT) | Approved | AI suggestion, approved by reviewer | 65% | The description's own words did not point to P090804010206. Similar devices registered in EUDAMED use this code (5 manufacturers, 334 registrations, 22% of filings, registered name similar in meaning to "quill pdo quill pdo polydioxanone"). Same product family, USP 3-0. A second check by another model could not be completed, so the first answer is shown. |
| Maximum number of reuses (FLD-UDID-157) | 0 | Approved | Derived by rule, approved by reviewer | 100% | Derived: device is labelled single use (FLD-UDID-167 = true), so maximum reuses is 0. |

| Field | Value | Status | Source | Confidence | Reasoning |
|---|---|---|---|---|---|
| Sterilisation method (FLD-UDID-165) | ETO | Approved | Exact column match, approved in a bulk review | 100% | Column "Sterilisationsverfahren" matched "Sterilisation method" exactly. |

## 4. Human Overrides

No override by a reviewer was recorded. Section 4.1 lists every recorded change to this device, including approvals and other edits.

## 4.1 Change history

The device was imported at 2026-10-08 21:38:43 UTC with 38 fields (event #43). Each line is one recorded change, oldest first. The event number is its position in this project's audit trail.

**Nomenclature code (EMDN) (FLD-UDID-149)**

- 2026-10-08 21:38:45 UTC. The AI classifier, run by ra.manager@beispiel-medizintechnik.de, set a new suggestion. (empty) -> "P090804010206" (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH MODULAR NECK, STRAIGHT). Event #45.
- 2026-10-08 21:39:36 UTC. ra.manager@beispiel-medizintechnik.de approved "P090804010206" (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH MODULAR NECK, STRAIGHT). The AI had suggested "P090804010206" (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH MODULAR NECK, STRAIGHT) with 65% confidence in event #44. Event #96.

**Maximum number of reuses (FLD-UDID-157)**

- 2026-10-08 21:38:45 UTC. The AI classifier, run by ra.manager@beispiel-medizintechnik.de, set a new suggestion. (empty) -> "0". Event #45.
- 2026-10-08 21:39:37 UTC. ra.manager@beispiel-medizintechnik.de approved "0". Event #97.

**Device Name (FLD-UDID-22)**

- 2026-10-08 21:39:14 UTC. ra.manager@beispiel-medizintechnik.de approved "Zementfreier Hüftschaft Größe 8" in bulk review B-07A2C765. Event #74.

**Applicable Legislation (FLD-UDID-11)**

- 2026-10-08 21:39:14 UTC. ra.manager@beispiel-medizintechnik.de approved "MDR" in bulk review B-07A2C765. Event #74.

**Risk Class (FLD-UDID-16)**

- 2026-10-08 21:39:14 UTC. ra.manager@beispiel-medizintechnik.de approved "CLASS_III" in bulk review B-07A2C765. Event #74.

**Legal Manufacturer SRN (FLD-UDID-10)**

- 2026-10-08 21:39:14 UTC. ra.manager@beispiel-medizintechnik.de approved "DE-MF-000000042" in bulk review B-07A2C765. Event #74.

**Implantable (FLD-UDID-30)**

- 2026-10-08 21:39:14 UTC. ra.manager@beispiel-medizintechnik.de approved "true" in bulk review B-07A2C765. Event #74.

**Active Device (FLD-UDID-28)**

- 2026-10-08 21:39:14 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #74.

**Measuring Function (FLD-UDID-31)**

- 2026-10-08 21:39:14 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #74.

**Reusable Surgical Instruments (FLD-UDID-32)**

- 2026-10-08 21:39:14 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #74.

**Presence of animal tissues or cells (FLD-UDID-18)**

- 2026-10-08 21:39:14 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #74.

**Presence of human tissues or cells (FLD-UDID-23)**

- 2026-10-08 21:39:14 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #74.

**Device intended to administer medicinal product (FLD-UDID-29)**

- 2026-10-08 21:39:14 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #74.

**Substance - may be considered medicinal product (FLD-UDID-158)**

- 2026-10-08 21:39:14 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #74.

**Reference / Catalogue number (FLD-UDID-163)**

- 2026-10-08 21:39:14 UTC. ra.manager@beispiel-medizintechnik.de approved "ART-1008" in bulk review B-07A2C765. Event #74.

**Trade name (FLD-UDID-176)**

- 2026-10-08 21:39:14 UTC. ra.manager@beispiel-medizintechnik.de approved "DE: OrthoFlex Hip Stem Größe 8" in bulk review B-07A2C765. Event #74.

**UDI-DI code (FLD-UDID-178)**

- 2026-10-08 21:39:14 UTC. ra.manager@beispiel-medizintechnik.de approved "04011616010082" in bulk review B-07A2C765. Event #74.

**Device labelled sterile (FLD-UDID-169)**

- 2026-10-08 21:39:14 UTC. ra.manager@beispiel-medizintechnik.de approved "true" in bulk review B-07A2C765. Event #74.

**Need for sterilisation before use (FLD-UDID-170)**

- 2026-10-08 21:39:14 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #74.

**Labelled as single use (FLD-UDID-167)**

- 2026-10-08 21:39:14 UTC. ra.manager@beispiel-medizintechnik.de approved "true" in bulk review B-07A2C765. Event #74.

**Reprocessed single use device (FLD-UDID-164)**

- 2026-10-08 21:39:14 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #74.

**Containing latex (FLD-UDID-156)**

- 2026-10-08 21:39:14 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #74.

**Device Status (FLD-UDID-130)**

- 2026-10-08 21:39:14 UTC. ra.manager@beispiel-medizintechnik.de approved "ON_THE_MARKET" in bulk review B-07A2C765. Event #74.

**Type of UDI-PI (Production Identifier) (FLD-UDID-148)**

- 2026-10-08 21:39:14 UTC. ra.manager@beispiel-medizintechnik.de approved "SERIALISATION_NUMBER" in bulk review B-07A2C765. Event #74.

**Quantity of device (FLD-UDID-151)**

- 2026-10-08 21:39:14 UTC. ra.manager@beispiel-medizintechnik.de approved "1" in bulk review B-07A2C765. Event #74.

**Certificate Type (FLD-UDID-60)**

- 2026-10-08 21:39:14 UTC. ra.manager@beispiel-medizintechnik.de approved "MDR_TYPE_EXAMINATION" in bulk review B-07A2C765. Event #74.

**Certificate Number (FLD-UDID-61)**

- 2026-10-08 21:39:14 UTC. ra.manager@beispiel-medizintechnik.de approved "0123/2022/045678" in bulk review B-07A2C765. Event #74.

**Notified Body (Certificate) (FLD-UDID-63)**

- 2026-10-08 21:39:14 UTC. ra.manager@beispiel-medizintechnik.de approved "0123" in bulk review B-07A2C765. Event #74.

**Certificate Expiry Date (FLD-UDID-64)**

- 2026-10-08 21:39:14 UTC. ra.manager@beispiel-medizintechnik.de approved "2027-04-30" in bulk review B-07A2C765. Event #74.

**Member State where device is available (FLD-UDID-252)**

- 2026-10-08 21:39:14 UTC. ra.manager@beispiel-medizintechnik.de approved "DE,AT,FR,IT,ES,NL,BE,PL" in bulk review B-07A2C765. Event #74.

**Basic UDI-DI code (FLD-UDID-14)**

- 2026-10-08 21:39:14 UTC. ra.manager@beispiel-medizintechnik.de approved "401161600010X5" in bulk review B-07A2C765. Event #74.

**Substance - human blood or plasma derived (FLD-UDID-155)**

- 2026-10-08 21:39:14 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #74.

**Market Info Start date (FLD-UDID-250)**

- 2026-10-08 21:39:14 UTC. ra.manager@beispiel-medizintechnik.de approved "2023-06-15" in bulk review B-07A2C765. Event #74.

**Issuing Entity Basic UDI-DI (FLD-UDID-01)**

- 2026-10-08 21:39:14 UTC. ra.manager@beispiel-medizintechnik.de approved "GS1" in bulk review B-07A2C765. Event #74.

**Issuing Entity UDI-DI (FLD-UDID-291)**

- 2026-10-08 21:39:14 UTC. ra.manager@beispiel-medizintechnik.de approved "GS1" in bulk review B-07A2C765. Event #74.

**System/Procedure Pack Type (FLD-UDID-12)**

- 2026-10-08 21:39:14 UTC. ra.manager@beispiel-medizintechnik.de approved "DEVICE" in bulk review B-07A2C765. Event #74.

**Member State of first placing on EU market (FLD-UDID-137)**

- 2026-10-08 21:39:14 UTC. ra.manager@beispiel-medizintechnik.de approved "DE" in bulk review B-07A2C765. Event #74.

**Sterilisation method (FLD-UDID-165)**

- 2026-10-08 21:39:14 UTC. ra.manager@beispiel-medizintechnik.de approved "ETO" in bulk review B-07A2C765. Event #74.

## 5. Validation History

- At upload, 2026-10-08 21:38:03 UTC. The rule check found 1 error(s) for this device
  - Error BR-MANDATORY, FLD-UDID-149. The rule check reported "Mandatory field missing for MDR".
- At export, 2026-10-08 21:40:02 UTC. 0 error(s), 0 warning(s) for this device under MDR
  - Language of a text. Trade name (FLD-UDID-176) is DE. The language code was written before the text in the uploaded file.
  - Passed EUDAMED's XSD format check.
- **Final status:** PASSED at export (2026-10-08 21:40:02 UTC). No rule errors, 0 warning(s), XSD check passed.

## 6. Milestones

- **Snapshot at upload** by ra.manager@beispiel-medizintechnik.de at 2026-10-08 21:38:42 UTC
- **Snapshot at export** by ra.manager@beispiel-medizintechnik.de at 2026-10-08 21:40:03 UTC

## 7. Full Timeline

- 2026-10-08 21:38:01 UTC. **File uploaded.** sample_catalogue.csv, 14 rows
- 2026-10-08 21:38:02 UTC. **Columns mapped.** 38 of 40 columns mapped (95%)
- 2026-10-08 21:38:03 UTC. **Validation at upload.** 1 error(s) for this device
- 2026-10-08 21:38:41 UTC. **Legislation determined.** MDR, stated in the uploaded file (FLD-UDID-11 as supplied (MDR))
- 2026-10-08 21:38:42 UTC. **Snapshot.** Snapshot at upload, by ra.manager@beispiel-medizintechnik.de
- 2026-10-08 21:38:43 UTC. **Device imported.** 38 fields imported, event #43
- 2026-10-08 21:38:44 UTC. **AI EMDN suggestion.** AI suggested P090804010206 (65% confidence)
- 2026-10-08 21:38:45 UTC. **Field change.** 2 field change(s) by the AI classifier, event #45
- 2026-10-08 21:39:14 UTC. **Field change.** 36 field change(s) by ra.manager@beispiel-medizintechnik.de, event #74
- 2026-10-08 21:39:36 UTC. **Field change.** 1 field change(s) by ra.manager@beispiel-medizintechnik.de, event #96
- 2026-10-08 21:39:37 UTC. **Field change.** 1 field change(s) by ra.manager@beispiel-medizintechnik.de, event #97
- 2026-10-08 21:40:02 UTC. **Validation at export.** 0 error(s), 0 warning(s). XSD check passed
- 2026-10-08 21:40:03 UTC. **Snapshot.** Snapshot at export, by ra.manager@beispiel-medizintechnik.de

# Device ART-1009, UDI-DI 04011616010099, "Zementfreier Hüftschaft Größe 9"

**Reference number:** ART-1009
**Device UDI-DI:** 04011616010099
**Name:** Zementfreier Hüftschaft Größe 9
**Legislation:** MDR, stated in the uploaded file
**Reviewed by:** ra.manager@beispiel-medizintechnik.de on 2026-10-08 21:39:39 UTC
**Events in this record:** 13

## 1. Data Provenance

- **sample_catalogue.csv** (csv, 14 rows), uploaded 2026-10-08 21:38:01 UTC

## 2. Column Mapping

- Mapped: 38 of 40 columns (95%)
- By method: exact match 33, normalised name 1, alias 0, AI 4
- Mandatory fields with no source column at upload: Nomenclature code (EMDN)

## 3. EMDN Classification

- **Confirmed by reviewer, the AI suggestion:** P090804010207 (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH MODULAR NECK, ANATOMICAL), AI confidence 90%
  - AI reasoning: Description states 'zementfrei' (uncemented) and 'Hüftschaft' (hip stem), so the code is supported. Neck type is not stated. A second check by another model could not be completed, so the first answer is shown.
  - Other codes listed for comparison. Their search match is not the confidence printed above. P090804010201 (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH FIXED NECK, STRAIGHT) (search match 19%); P090804010202 (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH FIXED NECK, ANATOMICAL) (search match 65%); P090804010206 (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH MODULAR NECK, STRAIGHT) (search match 65%); P090804030201 (REVISION UNCEMENTED FEMORAL STEMS, WITH FIXED NECK) (search match 62%)

## 3.5 Field-Level Reasoning

Each value below shows the source column, rule, reviewer action or AI rationale that produced it.

| Field | Value | Status | Source | Confidence | Reasoning |
|---|---|---|---|---|---|
| Device Name (FLD-UDID-22) | Zementfreier Hüftschaft Größe 9 | Approved | Exact column match, approved in a bulk review | 100% | Column "Bezeichnung" matched "Device Name" exactly. |
| Applicable Legislation (FLD-UDID-11) | MDR | Approved | Exact column match, approved in a bulk review | 100% | Column "Rechtsgrundlage" matched "Applicable Legislation" exactly. |

| Field | Value | Status | Source | Confidence | Reasoning |
|---|---|---|---|---|---|
| Risk Class (FLD-UDID-16) | Class III (CLASS_III) | Approved | Exact column match, approved in a bulk review | 100% | Column "Risikoklasse" matched "Risk Class" exactly. |
| Legal Manufacturer SRN (FLD-UDID-10) | DE-MF-000000042 | Approved | Exact column match, approved in a bulk review | 100% | Column "Hersteller-SRN" matched "Legal Manufacturer SRN" exactly. |
| Implantable (FLD-UDID-30) | true | Approved | Exact column match, approved in a bulk review | 100% | Column "Implantierbar" matched "Implantable" exactly. |
| Active Device (FLD-UDID-28) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Aktives Medizinprodukt" matched "Active Device" exactly. |
| Measuring Function (FLD-UDID-31) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Messfunktion" matched "Measuring Function" exactly. |
| Reusable Surgical Instruments (FLD-UDID-32) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Wiederverwendbar" matched "Reusable Surgical Instruments" exactly. |
| Presence of animal tissues or cells (FLD-UDID-18) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Tierisches Gewebe" matched "Presence of animal tissues or cells" exactly. |
| Presence of human tissues or cells (FLD-UDID-23) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Menschliches Gewebe" matched "Presence of human tissues or cells" exactly. |
| Device intended to administer medicinal product (FLD-UDID-29) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Arzneimittelabgabe" matched "Device intended to administer medicinal product" exactly. |
| Substance - may be considered medicinal product (FLD-UDID-158) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Arzneimittel" matched "Substance - may be considered medicinal product" exactly. |
| Reference / Catalogue number (FLD-UDID-163) | ART-1009 | Approved | Exact column match, approved in a bulk review | 100% | Column "Artikelnummer" matched "Reference / Catalogue number" exactly. |
| Trade name (FLD-UDID-176) | DE: OrthoFlex Hip Stem Größe 9 | Approved | Exact column match, approved in a bulk review | 100% | Column "Handelsname" matched "Trade name" exactly. |
| UDI-DI code (FLD-UDID-178) | 04011616010099 | Approved | Exact column match, approved in a bulk review | 100% | Column "GTIN" matched "UDI-DI code" exactly. |
| Device labelled sterile (FLD-UDID-169) | true | Approved | Exact column match, approved in a bulk review | 100% | Column "Steril" matched "Device labelled sterile" exactly. |

| Field | Value | Status | Source | Confidence | Reasoning |
|---|---|---|---|---|---|
| Need for sterilisation before use (FLD-UDID-170) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Sterilisation" matched "Need for sterilisation before use" exactly. |
| Labelled as single use (FLD-UDID-167) | true | Approved | Exact column match, approved in a bulk review | 100% | Column "Einmalgebrauch" matched "Labelled as single use" exactly. |
| Reprocessed single use device (FLD-UDID-164) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Aufbereitet" matched "Reprocessed single use device" exactly. |
| Containing latex (FLD-UDID-156) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Enthält Latex" matched "Containing latex" exactly. |
| Device Status (FLD-UDID-130) | On the market (ON_THE_MARKET) | Approved | Exact column match, approved in a bulk review | 100% | Column "Marktstatus" matched "Device Status" exactly. |
| Type of UDI-PI (Production Identifier) (FLD-UDID-148) | Serialisation number (SERIALISATION_NUMBER) | Approved | Exact column match, approved in a bulk review | 100% | Column "UDI-PI Typ" matched "Type of UDI-PI (Production Identifier)" exactly. |
| Quantity of device (FLD-UDID-151) | 1 | Approved | Exact column match, approved in a bulk review | 100% | Column "Menge" matched "Quantity of device" exactly. |
| Certificate Type (FLD-UDID-60) | MDR type examination (MDR_TYPE_EXAMINATION) | Approved | Exact column match, approved in a bulk review | 100% | Column "Zertifikattyp" matched "Certificate Type" exactly. |
| Certificate Number (FLD-UDID-61) | 0123/2022/045678 | Approved | Exact column match, approved in a bulk review | 100% | Column "Zertifikatsnummer" matched "Certificate Number" exactly. |
| Notified Body (Certificate) (FLD-UDID-63) | 0123 | Approved | Exact column match, approved in a bulk review | 100% | Column "Benannte Stelle" matched "Notified Body (Certificate)" exactly. |
| Certificate Expiry Date (FLD-UDID-64) | 2027-04-30 | Approved | Exact column match, approved in a bulk review | 100% | Column "Ablaufdatum Zertifikat" matched "Certificate Expiry Date" exactly. |
| Member State where device is available (FLD-UDID-252) | DE,AT,FR,IT,ES,NL,BE,PL | Approved | Exact column match, approved in a bulk review | 100% | Column "Vertriebsland" matched "Member State where device is available" exactly. |
| Basic UDI-DI code (FLD-UDID-14) | 401161600010X5 | Approved | Column match after normalising the name, approved in a bulk review | 95% | Column "Basic-UDI-DI" matched "Basic UDI-DI code" after normalising punctuation/case. |
| Substance - human blood or plasma derived (FLD-UDID-155) | false | Approved | AI column mapping, approved in a bulk review | 95% | AI mapped column "Blut- oder Plasmaderivat" to "Substance - human blood or plasma derived" (confidence 0.95). German for human blood or plasma derived substance |

| Field | Value | Status | Source | Confidence | Reasoning |
|---|---|---|---|---|---|
| Market Info Start date (FLD-UDID-250) | 2023-06-15 | Approved | AI column mapping, approved in a bulk review | 90% | AI mapped column "Marktverfügbarkeit ab" to "Market Info Start date" (confidence 0.90). Complements mapped Member State availability |
| Issuing Entity Basic UDI-DI (FLD-UDID-01) | GS1 | Approved | Derived by rule, approved in a bulk review | 100% | Inferred from Basic UDI-DI code format, "401161600010X5" is a GS1 identifier. |
| Issuing Entity UDI-DI (FLD-UDID-291) | GS1 | Approved | Derived by rule, approved in a bulk review | 100% | Inferred from UDI-DI code format, "04011616010099" is a GS1 identifier. |
| System/Procedure Pack Type (FLD-UDID-12) | DEVICE | Approved | Declared by the customer, approved in a bulk review | 100% | Declared at project level by the project owner: every device in this project is a device in itself, not a system or a procedure pack (MDR Art. 22). EUDAMED field FLD-UDID-12. |
| Member State of first placing on EU market (FLD-UDID-137) | DE | Approved | Declared by the customer, approved in a bulk review | 100% | Declared at project level by the project owner: the devices in this project were first placed on the EU market in DE. EUDAMED field FLD-UDID-137. |
| Nomenclature code (EMDN) (FLD-UDID-149) | P090804010207 (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH MODULAR NECK, ANATOMICAL) | Approved | AI suggestion, approved by reviewer | 90% | Description states 'zementfrei' (uncemented) and 'Hüftschaft' (hip stem), so the code is supported. Neck type is not stated. A second check by another model could not be completed, so the first answer is shown. |
| Maximum number of reuses (FLD-UDID-157) | 0 | Approved | Derived by rule, approved by reviewer | 100% | Derived: device is labelled single use (FLD-UDID-167 = true), so maximum reuses is 0. |
| Sterilisation method (FLD-UDID-165) | ETO | Approved | Exact column match, approved in a bulk review | 100% | Column "Sterilisationsverfahren" matched "Sterilisation method" exactly. |

## 4. Human Overrides

No override by a reviewer was recorded. Section 4.1 lists every recorded change to this device, including approvals and other edits.

## 4.1 Change history

The device was imported at 2026-10-08 21:38:48 UTC with 38 fields (event #48). Each line is one recorded change, oldest first. The event number is its position in this project's audit trail.

**Nomenclature code (EMDN) (FLD-UDID-149)**

- 2026-10-08 21:38:50 UTC. The AI classifier, run by ra.manager@beispiel-medizintechnik.de, set a new suggestion. (empty) -> "P090804010207" (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH MODULAR NECK, ANATOMICAL). Event #50.
- 2026-10-08 21:39:38 UTC. ra.manager@beispiel-medizintechnik.de approved "P090804010207" (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH MODULAR NECK, ANATOMICAL). The AI had suggested "P090804010207" (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH MODULAR NECK, ANATOMICAL) with 90% confidence in event #49. Event #98.

**Maximum number of reuses (FLD-UDID-157)**

- 2026-10-08 21:38:50 UTC. The AI classifier, run by ra.manager@beispiel-medizintechnik.de, set a new suggestion. (empty) -> "0". Event #50.
- 2026-10-08 21:39:39 UTC. ra.manager@beispiel-medizintechnik.de approved "0". Event #99.

**Device Name (FLD-UDID-22)**

- 2026-10-08 21:39:15 UTC. ra.manager@beispiel-medizintechnik.de approved "Zementfreier Hüftschaft Größe 9" in bulk review B-07A2C765. Event #75.

**Applicable Legislation (FLD-UDID-11)**

- 2026-10-08 21:39:15 UTC. ra.manager@beispiel-medizintechnik.de approved "MDR" in bulk review B-07A2C765. Event #75.

**Risk Class (FLD-UDID-16)**

- 2026-10-08 21:39:15 UTC. ra.manager@beispiel-medizintechnik.de approved "CLASS_III" in bulk review B-07A2C765. Event #75.

**Legal Manufacturer SRN (FLD-UDID-10)**

- 2026-10-08 21:39:15 UTC. ra.manager@beispiel-medizintechnik.de approved "DE-MF-000000042" in bulk review B-07A2C765. Event #75.

**Implantable (FLD-UDID-30)**

- 2026-10-08 21:39:15 UTC. ra.manager@beispiel-medizintechnik.de approved "true" in bulk review B-07A2C765. Event #75.

**Active Device (FLD-UDID-28)**

- 2026-10-08 21:39:15 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #75.

**Measuring Function (FLD-UDID-31)**

- 2026-10-08 21:39:15 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #75.

**Reusable Surgical Instruments (FLD-UDID-32)**

- 2026-10-08 21:39:15 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #75.

**Presence of animal tissues or cells (FLD-UDID-18)**

- 2026-10-08 21:39:15 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #75.

**Presence of human tissues or cells (FLD-UDID-23)**

- 2026-10-08 21:39:15 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #75.

**Device intended to administer medicinal product (FLD-UDID-29)**

- 2026-10-08 21:39:15 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #75.

**Substance - may be considered medicinal product (FLD-UDID-158)**

- 2026-10-08 21:39:15 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #75.

**Reference / Catalogue number (FLD-UDID-163)**

- 2026-10-08 21:39:15 UTC. ra.manager@beispiel-medizintechnik.de approved "ART-1009" in bulk review B-07A2C765. Event #75.

**Trade name (FLD-UDID-176)**

- 2026-10-08 21:39:15 UTC. ra.manager@beispiel-medizintechnik.de approved "DE: OrthoFlex Hip Stem Größe 9" in bulk review B-07A2C765. Event #75.

**UDI-DI code (FLD-UDID-178)**

- 2026-10-08 21:39:15 UTC. ra.manager@beispiel-medizintechnik.de approved "04011616010099" in bulk review B-07A2C765. Event #75.

**Device labelled sterile (FLD-UDID-169)**

- 2026-10-08 21:39:15 UTC. ra.manager@beispiel-medizintechnik.de approved "true" in bulk review B-07A2C765. Event #75.

**Need for sterilisation before use (FLD-UDID-170)**

- 2026-10-08 21:39:15 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #75.

**Labelled as single use (FLD-UDID-167)**

- 2026-10-08 21:39:15 UTC. ra.manager@beispiel-medizintechnik.de approved "true" in bulk review B-07A2C765. Event #75.

**Reprocessed single use device (FLD-UDID-164)**

- 2026-10-08 21:39:15 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #75.

**Containing latex (FLD-UDID-156)**

- 2026-10-08 21:39:15 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #75.

**Device Status (FLD-UDID-130)**

- 2026-10-08 21:39:15 UTC. ra.manager@beispiel-medizintechnik.de approved "ON_THE_MARKET" in bulk review B-07A2C765. Event #75.

**Type of UDI-PI (Production Identifier) (FLD-UDID-148)**

- 2026-10-08 21:39:15 UTC. ra.manager@beispiel-medizintechnik.de approved "SERIALISATION_NUMBER" in bulk review B-07A2C765. Event #75.

**Quantity of device (FLD-UDID-151)**

- 2026-10-08 21:39:15 UTC. ra.manager@beispiel-medizintechnik.de approved "1" in bulk review B-07A2C765. Event #75.

**Certificate Type (FLD-UDID-60)**

- 2026-10-08 21:39:15 UTC. ra.manager@beispiel-medizintechnik.de approved "MDR_TYPE_EXAMINATION" in bulk review B-07A2C765. Event #75.

**Certificate Number (FLD-UDID-61)**

- 2026-10-08 21:39:15 UTC. ra.manager@beispiel-medizintechnik.de approved "0123/2022/045678" in bulk review B-07A2C765. Event #75.

**Notified Body (Certificate) (FLD-UDID-63)**

- 2026-10-08 21:39:15 UTC. ra.manager@beispiel-medizintechnik.de approved "0123" in bulk review B-07A2C765. Event #75.

**Certificate Expiry Date (FLD-UDID-64)**

- 2026-10-08 21:39:15 UTC. ra.manager@beispiel-medizintechnik.de approved "2027-04-30" in bulk review B-07A2C765. Event #75.

**Member State where device is available (FLD-UDID-252)**

- 2026-10-08 21:39:15 UTC. ra.manager@beispiel-medizintechnik.de approved "DE,AT,FR,IT,ES,NL,BE,PL" in bulk review B-07A2C765. Event #75.

**Basic UDI-DI code (FLD-UDID-14)**

- 2026-10-08 21:39:15 UTC. ra.manager@beispiel-medizintechnik.de approved "401161600010X5" in bulk review B-07A2C765. Event #75.

**Substance - human blood or plasma derived (FLD-UDID-155)**

- 2026-10-08 21:39:15 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #75.

**Market Info Start date (FLD-UDID-250)**

- 2026-10-08 21:39:15 UTC. ra.manager@beispiel-medizintechnik.de approved "2023-06-15" in bulk review B-07A2C765. Event #75.

**Issuing Entity Basic UDI-DI (FLD-UDID-01)**

- 2026-10-08 21:39:15 UTC. ra.manager@beispiel-medizintechnik.de approved "GS1" in bulk review B-07A2C765. Event #75.

**Issuing Entity UDI-DI (FLD-UDID-291)**

- 2026-10-08 21:39:15 UTC. ra.manager@beispiel-medizintechnik.de approved "GS1" in bulk review B-07A2C765. Event #75.

**System/Procedure Pack Type (FLD-UDID-12)**

- 2026-10-08 21:39:15 UTC. ra.manager@beispiel-medizintechnik.de approved "DEVICE" in bulk review B-07A2C765. Event #75.

**Member State of first placing on EU market (FLD-UDID-137)**

- 2026-10-08 21:39:15 UTC. ra.manager@beispiel-medizintechnik.de approved "DE" in bulk review B-07A2C765. Event #75.

**Sterilisation method (FLD-UDID-165)**

- 2026-10-08 21:39:15 UTC. ra.manager@beispiel-medizintechnik.de approved "ETO" in bulk review B-07A2C765. Event #75.

## 5. Validation History

- At upload, 2026-10-08 21:38:03 UTC. The rule check found 1 error(s) for this device
  - Error BR-MANDATORY, FLD-UDID-149. The rule check reported "Mandatory field missing for MDR".
- At export, 2026-10-08 21:40:04 UTC. 0 error(s), 0 warning(s) for this device under MDR
  - Language of a text. Trade name (FLD-UDID-176) is DE. The language code was written before the text in the uploaded file.
  - Passed EUDAMED's XSD format check.
- **Final status:** PASSED at export (2026-10-08 21:40:04 UTC). No rule errors, 0 warning(s), XSD check passed.

## 6. Milestones

- **Snapshot at upload** by ra.manager@beispiel-medizintechnik.de at 2026-10-08 21:38:47 UTC
- **Snapshot at export** by ra.manager@beispiel-medizintechnik.de at 2026-10-08 21:40:05 UTC

## 7. Full Timeline

- 2026-10-08 21:38:01 UTC. **File uploaded.** sample_catalogue.csv, 14 rows
- 2026-10-08 21:38:02 UTC. **Columns mapped.** 38 of 40 columns mapped (95%)
- 2026-10-08 21:38:03 UTC. **Validation at upload.** 1 error(s) for this device
- 2026-10-08 21:38:46 UTC. **Legislation determined.** MDR, stated in the uploaded file (FLD-UDID-11 as supplied (MDR))
- 2026-10-08 21:38:47 UTC. **Snapshot.** Snapshot at upload, by ra.manager@beispiel-medizintechnik.de
- 2026-10-08 21:38:48 UTC. **Device imported.** 38 fields imported, event #48

- 2026-10-08 21:38:49 UTC. **AI EMDN suggestion.** AI suggested P090804010207 (90% confidence)
- 2026-10-08 21:38:50 UTC. **Field change.** 2 field change(s) by the AI classifier, event #50
- 2026-10-08 21:39:15 UTC. **Field change.** 36 field change(s) by ra.manager@beispiel-medizintechnik.de, event #75
- 2026-10-08 21:39:38 UTC. **Field change.** 1 field change(s) by ra.manager@beispiel-medizintechnik.de, event #98
- 2026-10-08 21:39:39 UTC. **Field change.** 1 field change(s) by ra.manager@beispiel-medizintechnik.de, event #99
- 2026-10-08 21:40:04 UTC. **Validation at export.** 0 error(s), 0 warning(s). XSD check passed
- 2026-10-08 21:40:05 UTC. **Snapshot.** Snapshot at export, by ra.manager@beispiel-medizintechnik.de

# Device ART-1010, UDI-DI 04011616010105, "Zementfreier Hüftschaft Größe 10"

**Reference number:** ART-1010
**Device UDI-DI:** 04011616010105
**Name:** Zementfreier Hüftschaft Größe 10
**Legislation:** MDR, stated in the uploaded file
**Reviewed by:** ra.manager@beispiel-medizintechnik.de on 2026-10-08 21:39:41 UTC
**Events in this record:** 13

## 1. Data Provenance

- **sample_catalogue.csv** (csv, 14 rows), uploaded 2026-10-08 21:38:01 UTC

## 2. Column Mapping

- Mapped: 38 of 40 columns (95%)
- By method: exact match 33, normalised name 1, alias 0, AI 4
- Mandatory fields with no source column at upload: Nomenclature code (EMDN)

## 3. EMDN Classification

- **Confirmed by reviewer, the AI suggestion:** P090804030201 (REVISION UNCEMENTED FEMORAL STEMS, WITH FIXED NECK), AI confidence 90%
  - AI reasoning: Description states 'zementfrei' (uncemented) and 'Hüftschaft' (hip stem), so the code is supported. Neck type is not stated. A second check by another model could not be completed, so the first answer is shown.
  - Other codes listed for comparison. Their search match is not the confidence printed above. P090804010201 (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH FIXED NECK, STRAIGHT) (search match 19%); P090804010202 (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH FIXED NECK, ANATOMICAL) (search match 65%); P090804010206 (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH MODULAR NECK, STRAIGHT) (search match 65%); P090804010207 (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH MODULAR NECK, ANATOMICAL) (search match 62%)

## 3.5 Field-Level Reasoning

Each value below shows the source column, rule, reviewer action or AI rationale that produced it.

| Field | Value | Status | Source | Confidence | Reasoning |
|---|---|---|---|---|---|
| Device Name (FLD-UDID-22) | Zementfreier Hüftschaft Größe 10 | Approved | Exact column match, approved in a bulk review | 100% | Column "Bezeichnung" matched "Device Name" exactly. |
| Applicable Legislation (FLD-UDID-11) | MDR | Approved | Exact column match, approved in a bulk review | 100% | Column "Rechtsgrundlage" matched "Applicable Legislation" exactly. |
| Risk Class (FLD-UDID-16) | Class III (CLASS_III) | Approved | Exact column match, approved in a bulk review | 100% | Column "Risikoklasse" matched "Risk Class" exactly. |
| Legal Manufacturer SRN (FLD-UDID-10) | DE-MF-000000042 | Approved | Exact column match, approved in a bulk review | 100% | Column "Hersteller-SRN" matched "Legal Manufacturer SRN" exactly. |
| Implantable (FLD-UDID-30) | true | Approved | Exact column match, approved in a bulk review | 100% | Column "Implantierbar" matched "Implantable" exactly. |
| Active Device (FLD-UDID-28) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Aktives Medizinprodukt" matched "Active Device" exactly. |
| Measuring Function (FLD-UDID-31) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Messfunktion" matched "Measuring Function" exactly. |
| Reusable Surgical Instruments (FLD-UDID-32) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Wiederverwendbar" matched "Reusable Surgical Instruments" exactly. |
| Presence of animal tissues or cells (FLD-UDID-18) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Tierisches Gewebe" matched "Presence of animal tissues or cells" exactly. |
| Presence of human tissues or cells (FLD-UDID-23) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Menschliches Gewebe" matched "Presence of human tissues or cells" exactly. |
| Device intended to administer medicinal product (FLD-UDID-29) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Arzneimittelabgabe" matched "Device intended to administer medicinal product" exactly. |
| Substance - may be considered medicinal product (FLD-UDID-158) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Arzneimittel" matched "Substance - may be considered medicinal product" exactly. |
| Reference / Catalogue number (FLD-UDID-163) | ART-1010 | Approved | Exact column match, approved in a bulk review | 100% | Column "Artikelnummer" matched "Reference / Catalogue number" exactly. |

| Field | Value | Status | Source | Confidence | Reasoning |
|---|---|---|---|---|---|
| Trade name (FLD-UDID-176) | DE: OrthoFlex Hip Stem Größe 10 | Approved | Exact column match, approved in a bulk review | 100% | Column "Handelsname" matched "Trade name" exactly. |
| UDI-DI code (FLD-UDID-178) | 04011616010105 | Approved | Exact column match, approved in a bulk review | 100% | Column "GTIN" matched "UDI-DI code" exactly. |
| Device labelled sterile (FLD-UDID-169) | true | Approved | Exact column match, approved in a bulk review | 100% | Column "Steril" matched "Device labelled sterile" exactly. |
| Need for sterilisation before use (FLD-UDID-170) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Sterilisation" matched "Need for sterilisation before use" exactly. |
| Labelled as single use (FLD-UDID-167) | true | Approved | Exact column match, approved in a bulk review | 100% | Column "Einmalgebrauch" matched "Labelled as single use" exactly. |
| Reprocessed single use device (FLD-UDID-164) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Aufbereitet" matched "Reprocessed single use device" exactly. |
| Containing latex (FLD-UDID-156) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Enthält Latex" matched "Containing latex" exactly. |
| Device Status (FLD-UDID-130) | On the market (ON_THE_MARKET) | Approved | Exact column match, approved in a bulk review | 100% | Column "Marktstatus" matched "Device Status" exactly. |
| Type of UDI-PI (Production Identifier) (FLD-UDID-148) | Serialisation number (SERIALISATION_NUMBER) | Approved | Exact column match, approved in a bulk review | 100% | Column "UDI-PI Typ" matched "Type of UDI-PI (Production Identifier)" exactly. |
| Quantity of device (FLD-UDID-151) | 1 | Approved | Exact column match, approved in a bulk review | 100% | Column "Menge" matched "Quantity of device" exactly. |
| Certificate Type (FLD-UDID-60) | MDR type examination (MDR_TYPE_EXAMINATION) | Approved | Exact column match, approved in a bulk review | 100% | Column "Zertifikattyp" matched "Certificate Type" exactly. |
| Certificate Number (FLD-UDID-61) | 0123/2022/045678 | Approved | Exact column match, approved in a bulk review | 100% | Column "Zertifikatsnummer" matched "Certificate Number" exactly. |
| Notified Body (Certificate) (FLD-UDID-63) | 0434 | Approved | Exact column match, approved in a bulk review | 100% | Column "Benannte Stelle" matched "Notified Body (Certificate)" exactly. |
| Certificate Expiry Date (FLD-UDID-64) | 2027-04-30 | Approved | Exact column match, approved in a bulk review | 100% | Column "Ablaufdatum Zertifikat" matched "Certificate Expiry Date" exactly. |
| Member State where device is available (FLD-UDID-252) | DE,AT,FR,IT,ES,NL,BE,PL | Approved | Exact column match, approved in a bulk review | 100% | Column "Vertriebsland" matched "Member State where device is available" exactly. |
| Basic UDI-DI code (FLD-UDID-14) | 401161600010X5 | Approved | Column match after normalising the name, approved in a bulk review | 95% | Column "Basic-UDI-DI" matched "Basic UDI-DI code" after normalising punctuation/case. |

| Field | Value | Status | Source | Confidence | Reasoning |
|---|---|---|---|---|---|
| Substance - human blood or plasma derived (FLD-UDID-155) | false | Approved | AI column mapping, approved in a bulk review | 95% | AI mapped column "Blut- oder Plasmaderivat" to "Substance - human blood or plasma derived" (confidence 0.95). German for human blood or plasma derived substance |
| Market Info Start date (FLD-UDID-250) | 2023-06-15 | Approved | AI column mapping, approved in a bulk review | 90% | AI mapped column "Marktverfügbarkeit ab" to "Market Info Start date" (confidence 0.90). Complements mapped Member State availability |
| Issuing Entity Basic UDI-DI (FLD-UDID-01) | GS1 | Approved | Derived by rule, approved in a bulk review | 100% | Inferred from Basic UDI-DI code format, "401161600010X5" is a GS1 identifier. |
| Issuing Entity UDI-DI (FLD-UDID-291) | GS1 | Approved | Derived by rule, approved in a bulk review | 100% | Inferred from UDI-DI code format, "04011616010105" is a GS1 identifier. |
| System/Procedure Pack Type (FLD-UDID-12) | DEVICE | Approved | Declared by the customer, approved in a bulk review | 100% | Declared at project level by the project owner: every device in this project is a device in itself, not a system or a procedure pack (MDR Art. 22). EUDAMED field FLD-UDID-12. |
| Member State of first placing on EU market (FLD-UDID-137) | DE | Approved | Declared by the customer, approved in a bulk review | 100% | Declared at project level by the project owner: the devices in this project were first placed on the EU market in DE. EUDAMED field FLD-UDID-137. |
| Nomenclature code (EMDN) (FLD-UDID-149) | P090804030201 (REVISION UNCEMENTED FEMORAL STEMS, WITH FIXED NECK) | Approved | AI suggestion, approved by reviewer | 90% | Description states 'zement frei' (uncemented) and 'Hüftschaft' (hip stem), so the code is supported. Neck type is not stated. A second check by another model could not be completed, so the first answer is shown. |
| Maximum number of reuses (FLD-UDID-157) | 0 | Approved | Derived by rule, approved by reviewer | 100% | Derived: device is labelled single use (FLD-UDID-167 = true), so maximum reuses is 0. |
| Sterilisation method (FLD-UDID-165) | ETO | Approved | Exact column match, approved in a bulk review | 100% | Column "Sterilisationsverfahren" matched "Sterilisation method" exactly. |

## 4. Human Overrides

No override by a reviewer was recorded. Section 4.1 lists every recorded change to this device, including approvals and other edits.

## 4.1 Change history

The device was imported at 2026-10-08 21:38:53 UTC with 38 fields (event #53). Each line is one recorded change, oldest first. The event number is its position in this project's audit trail.

**Nomenclature code (EMDN) (FLD-UDID-149)**

- 2026-10-08 21:38:55 UTC. The AI classifier, run by ra.manager@beispiel-medizintechnik.de, set a new suggestion. (empty) -> "P090804030201" (REVISION UNCEMENTED FEMORAL STEMS, WITH FIXED NECK). Event #55.
- 2026-10-08 21:39:40 UTC. ra.manager@beispiel-medizintechnik.de approved "P090804030201" (REVISION UNCEMENTED FEMORAL STEMS, WITH FIXED NECK). The AI had suggested "P090804030201" (REVISION UNCEMENTED FEMORAL STEMS, WITH FIXED NECK) with 90% confidence in event #54. Event #100.

**Maximum number of reuses (FLD-UDID-157)**

- 2026-10-08 21:38:55 UTC. The AI classifier, run by ra.manager@beispiel-medizintechnik.de, set a new suggestion. (empty) -> "0". Event #55.
- 2026-10-08 21:39:41 UTC. ra.manager@beispiel-medizintechnik.de approved "0". Event #101.

**Device Name (FLD-UDID-22)**

- 2026-10-08 21:39:16 UTC. ra.manager@beispiel-medizintechnik.de approved "Zementfreier Hüftschaft Größe 10" in bulk review B-07A2C765. Event #76.

**Applicable Legislation (FLD-UDID-11)**

- 2026-10-08 21:39:16 UTC. ra.manager@beispiel-medizintechnik.de approved "MDR" in bulk review B-07A2C765. Event #76.

**Risk Class (FLD-UDID-16)**

- 2026-10-08 21:39:16 UTC. ra.manager@beispiel-medizintechnik.de approved "CLASS_III" in bulk review B-07A2C765. Event #76.

**Legal Manufacturer SRN (FLD-UDID-10)**

- 2026-10-08 21:39:16 UTC. ra.manager@beispiel-medizintechnik.de approved "DE-MF-000000042" in bulk review B-07A2C765. Event #76.

**Implantable (FLD-UDID-30)**

- 2026-10-08 21:39:16 UTC. ra.manager@beispiel-medizintechnik.de approved "true" in bulk review B-07A2C765. Event #76.

**Active Device (FLD-UDID-28)**

- 2026-10-08 21:39:16 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #76.

**Measuring Function (FLD-UDID-31)**

- 2026-10-08 21:39:16 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #76.

**Reusable Surgical Instruments (FLD-UDID-32)**

- 2026-10-08 21:39:16 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #76.

**Presence of animal tissues or cells (FLD-UDID-18)**

- 2026-10-08 21:39:16 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #76.

**Presence of human tissues or cells (FLD-UDID-23)**

- 2026-10-08 21:39:16 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #76.

**Device intended to administer medicinal product (FLD-UDID-29)**

- 2026-10-08 21:39:16 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #76.

**Substance - may be considered medicinal product (FLD-UDID-158)**

- 2026-10-08 21:39:16 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #76.

**Reference / Catalogue number (FLD-UDID-163)**

- 2026-10-08 21:39:16 UTC. ra.manager@beispiel-medizintechnik.de approved "ART-1010" in bulk review B-07A2C765. Event #76.

**Trade name (FLD-UDID-176)**

- 2026-10-08 21:39:16 UTC. ra.manager@beispiel-medizintechnik.de approved "DE: OrthoFlex Hip Stem Größe 10" in bulk review B-07A2C765. Event #76.

**UDI-DI code (FLD-UDID-178)**

- 2026-10-08 21:39:16 UTC. ra.manager@beispiel-medizintechnik.de approved "04011616010105" in bulk review B-07A2C765. Event #76.

**Device labelled sterile (FLD-UDID-169)**

- 2026-10-08 21:39:16 UTC. ra.manager@beispiel-medizintechnik.de approved "true" in bulk review B-07A2C765. Event #76.

**Need for sterilisation before use (FLD-UDID-170)**

- 2026-10-08 21:39:16 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #76.

**Labelled as single use (FLD-UDID-167)**

- 2026-10-08 21:39:16 UTC. ra.manager@beispiel-medizintechnik.de approved "true" in bulk review B-07A2C765. Event #76.

**Reprocessed single use device (FLD-UDID-164)**

- 2026-10-08 21:39:16 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #76.

**Containing latex (FLD-UDID-156)**

- 2026-10-08 21:39:16 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #76.

**Device Status (FLD-UDID-130)**

- 2026-10-08 21:39:16 UTC. ra.manager@beispiel-medizintechnik.de approved "ON_THE_MARKET" in bulk review B-07A2C765. Event #76.

**Type of UDI-PI (Production Identifier) (FLD-UDID-148)**

- 2026-10-08 21:39:16 UTC. ra.manager@beispiel-medizintechnik.de approved "SERIALISATION_NUMBER" in bulk review B-07A2C765. Event #76.

**Quantity of device (FLD-UDID-151)**

- 2026-10-08 21:39:16 UTC. ra.manager@beispiel-medizintechnik.de approved "1" in bulk review B-07A2C765. Event #76.

**Certificate Type (FLD-UDID-60)**

- 2026-10-08 21:39:16 UTC. ra.manager@beispiel-medizintechnik.de approved "MDR_TYPE_EXAMINATION" in bulk review B-07A2C765. Event #76.

**Certificate Number (FLD-UDID-61)**

- 2026-10-08 21:39:16 UTC. ra.manager@beispiel-medizintechnik.de approved "0123/2022/045678" in bulk review B-07A2C765. Event #76.

**Notified Body (Certificate) (FLD-UDID-63)**

- 2026-10-08 21:39:16 UTC. ra.manager@beispiel-medizintechnik.de approved "0434" in bulk review B-07A2C765. Event #76.

**Certificate Expiry Date (FLD-UDID-64)**

- 2026-10-08 21:39:16 UTC. ra.manager@beispiel-medizintechnik.de approved "2027-04-30" in bulk review B-07A2C765. Event #76.

**Member State where device is available (FLD-UDID-252)**

- 2026-10-08 21:39:16 UTC. ra.manager@beispiel-medizintechnik.de approved "DE,AT,FR,IT,ES,NL,BE,PL" in bulk review B-07A2C765. Event #76.

**Basic UDI-DI code (FLD-UDID-14)**

- 2026-10-08 21:39:16 UTC. ra.manager@beispiel-medizintechnik.de approved "401161600010X5" in bulk review B-07A2C765. Event #76.

**Substance - human blood or plasma derived (FLD-UDID-155)**

- 2026-10-08 21:39:16 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #76.

**Market Info Start date (FLD-UDID-250)**

- 2026-10-08 21:39:16 UTC. ra.manager@beispiel-medizintechnik.de approved "2023-06-15" in bulk review B-07A2C765. Event #76.

**Issuing Entity Basic UDI-DI (FLD-UDID-01)**

- 2026-10-08 21:39:16 UTC. ra.manager@beispiel-medizintechnik.de approved "GS1" in bulk review B-07A2C765. Event #76.

**Issuing Entity UDI-DI (FLD-UDID-291)**

- 2026-10-08 21:39:16 UTC. ra.manager@beispiel-medizintechnik.de approved "GS1" in bulk review B-07A2C765. Event #76.

**System/Procedure Pack Type (FLD-UDID-12)**

- 2026-10-08 21:39:16 UTC. ra.manager@beispiel-medizintechnik.de approved "DEVICE" in bulk review B-07A2C765. Event #76.

**Member State of first placing on EU market (FLD-UDID-137)**

- 2026-10-08 21:39:16 UTC. ra.manager@beispiel-medizintechnik.de approved "DE" in bulk review B-07A2C765. Event #76.

**Sterilisation method (FLD-UDID-165)**

- 2026-10-08 21:39:16 UTC. ra.manager@beispiel-medizintechnik.de approved "ETO" in bulk review B-07A2C765. Event #76.

## 5. Validation History

- At upload, 2026-10-08 21:38:03 UTC. The rule check found 1 error(s) for this device
  - Error BR-MANDATORY, FLD-UDID-149. The rule check reported "Mandatory field missing for MDR".
- At export, 2026-10-08 21:40:06 UTC. 0 error(s), 1 warning(s) for this device under MDR
  - Warning pre-export check, FLD-UDID-63. The rule check reported "Notified Body code "0434" is not in the NANDO registry of designated notified bodies. Confirm the notified body before submission.".
  - Language of a text. Trade name (FLD-UDID-176) is DE. The language code was written before the text in the uploaded file.
  - Passed EUDAMED's XSD format check.
- **Final status:** PASSED at export (2026-10-08 21:40:06 UTC). No rule errors, 1 warning(s), XSD check passed.

## 6. Milestones

- **Snapshot at upload** by ra.manager@beispiel-medizintechnik.de at 2026-10-08 21:38:52 UTC
- **Snapshot at export** by ra.manager@beispiel-medizintechnik.de at 2026-10-08 21:40:07 UTC

## 7. Full Timeline

- 2026-10-08 21:38:01 UTC. **File uploaded.** sample_catalogue.csv, 14 rows
- 2026-10-08 21:38:02 UTC. **Columns mapped.** 38 of 40 columns mapped (95%)

- 2026-10-08 21:38:03 UTC. **Validation at upload.** 1 error(s) for this device
- 2026-10-08 21:38:51 UTC. **Legislation determined.** MDR, stated in the uploaded file (FLD-UDID-11 as supplied (MDR))
- 2026-10-08 21:38:52 UTC. **Snapshot.** Snapshot at upload, by ra.manager@beispiel-medizintechnik.de
- 2026-10-08 21:38:53 UTC. **Device imported.** 38 fields imported, event #53
- 2026-10-08 21:38:54 UTC. **AI EMDN suggestion.** AI suggested P090804030201 (90% confidence)
- 2026-10-08 21:38:55 UTC. **Field change.** 2 field change(s) by the AI classifier, event #55
- 2026-10-08 21:39:16 UTC. **Field change.** 36 field change(s) by ra.manager@beispiel-medizintechnik.de, event #76
- 2026-10-08 21:39:40 UTC. **Field change.** 1 field change(s) by ra.manager@beispiel-medizintechnik.de, event #100
- 2026-10-08 21:39:41 UTC. **Field change.** 1 field change(s) by ra.manager@beispiel-medizintechnik.de, event #101
- 2026-10-08 21:40:06 UTC. **Validation at export.** 0 error(s), 1 warning(s). XSD check passed
- 2026-10-08 21:40:07 UTC. **Snapshot.** Snapshot at export, by ra.manager@beispiel-medizintechnik.de

# Device ART-1011, UDI-DI 04011616010112, "Zementfreier Hüftschaft Größe 11"

**Reference number:** ART-1011
**Device UDI-DI:** 04011616010112
**Name:** Zementfreier Hüftschaft Größe 11
**Legislation:** MDR, stated in the uploaded file
**Reviewed by:** ra.manager@beispiel-medizintechnik.de on 2026-10-08 21:39:43 UTC
**Events in this record:** 13

## 1. Data Provenance

- **sample_catalogue.csv** (csv, 14 rows), uploaded 2026-10-08 21:38:01 UTC

## 2. Column Mapping

- Mapped: 38 of 40 columns (95%)
- By method: exact match 33, normalised name 1, alias 0, AI 4
- Mandatory fields with no source column at upload: Nomenclature code (EMDN)

## 3. EMDN Classification

- **Confirmed by reviewer, the AI suggestion:** P090804010201 (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH FIXED NECK, STRAIGHT), AI confidence 65%
  - AI reasoning: The description's own words did not point to P090804010201. Similar devices registered in EUDAMED use this code (5 manufacturers, 334 registrations, 22% of filings, registered name similar in meaning to "quill pdo quill pdo polydioxanone"). Same product family, USP 3-0. A second check by another model could not be completed, so the first answer is shown.
  - Other codes listed for comparison. Their search match is not the confidence printed above. P090804010202 (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH FIXED NECK, ANATOMICAL) (search match 19%); P090804010206 (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH MODULAR NECK, STRAIGHT) (search match 65%); P090804010207 (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH MODULAR NECK, ANATOMICAL) (search match 65%); P090804030201 (REVISION UNCEMENTED FEMORAL STEMS, WITH FIXED NECK) (search match 62%)

## 3.5 Field-Level Reasoning

Each value below shows the source column, rule, reviewer action or AI rationale that produced it.

| Field | Value | Status | Source | Confidence | Reasoning |
|---|---|---|---|---|---|
| Device Name (FLD-UDID-22) | Zementfreier Hüftschaft Größe 11 | Approved | Exact column match, approved in a bulk review | 100% | Column "Bezeichnung" matched "Device Name" exactly. |
| Applicable Legislation (FLD-UDID-11) | MDR | Approved | Exact column match, approved in a bulk review | 100% | Column "Rechtsgrundlage" matched "Applicable Legislation" exactly. |
| Risk Class (FLD-UDID-16) | Class III (CLASS_III) | Approved | Exact column match, approved in a bulk review | 100% | Column "Risikoklasse" matched "Risk Class" exactly. |
| Legal Manufacturer SRN (FLD-UDID-10) | DE-MF-000000042 | Approved | Exact column match, approved in a bulk review | 100% | Column "Hersteller-SRN" matched "Legal Manufacturer SRN" exactly. |
| Implantable (FLD-UDID-30) | true | Approved | Exact column match, approved in a bulk review | 100% | Column "Implantierbar" matched "Implantable" exactly. |
| Active Device (FLD-UDID-28) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Aktives Medizinprodukt" matched "Active Device" exactly. |
| Measuring Function (FLD-UDID-31) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Messfunktion" matched "Measuring Function" exactly. |
| Reusable Surgical Instruments (FLD-UDID-32) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Wiederverwendbar" matched "Reusable Surgical Instruments" exactly. |
| Presence of animal tissues or cells (FLD-UDID-18) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Tierisches Gewebe" matched "Presence of animal tissues or cells" exactly. |
| Presence of human tissues or cells (FLD-UDID-23) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Menschliches Gewebe" matched "Presence of human tissues or cells" exactly. |
| Device intended to administer medicinal product (FLD-UDID-29) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Arzneimittelabgabe" matched "Device intended to administer medicinal product" exactly. |
| Substance - may be considered medicinal product (FLD-UDID-158) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Arzneimittel" matched "Substance - may be considered medicinal product" exactly. |
| Reference / Catalogue number (FLD-UDID-163) | ART-1011 | Approved | Exact column match, approved in a bulk review | 100% | Column "Artikelnummer" matched "Reference / Catalogue number" exactly. |

| Field | Value | Status | Source | Confidence | Reasoning |
|---|---|---|---|---|---|
| Trade name (FLD-UDID-176) | DE: OrthoFlex Hip Stem Größe 11 | Approved | Exact column match, approved in a bulk review | 100% | Column "Handelsname" matched "Trade name" exactly. |
| UDI-DI code (FLD-UDID-178) | 04011616010112 | Approved | Exact column match, approved in a bulk review | 100% | Column "GTIN" matched "UDI-DI code" exactly. |
| Device labelled sterile (FLD-UDID-169) | true | Approved | Exact column match, approved in a bulk review | 100% | Column "Steril" matched "Device labelled sterile" exactly. |
| Need for sterilisation before use (FLD-UDID-170) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Sterilisation" matched "Need for sterilisation before use" exactly. |
| Labelled as single use (FLD-UDID-167) | true | Approved | Exact column match, approved in a bulk review | 100% | Column "Einmalgebrauch" matched "Labelled as single use" exactly. |
| Reprocessed single use device (FLD-UDID-164) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Aufbereitet" matched "Reprocessed single use device" exactly. |
| Containing latex (FLD-UDID-156) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Enthält Latex" matched "Containing latex" exactly. |
| Device Status (FLD-UDID-130) | On the market (ON_THE_MARKET) | Approved | Exact column match, approved in a bulk review | 100% | Column "Marktstatus" matched "Device Status" exactly. |
| Type of UDI-PI (Production Identifier) (FLD-UDID-148) | Serialisation number (SERIALISATION_NUMBER) | Approved | Exact column match, approved in a bulk review | 100% | Column "UDI-PI Typ" matched "Type of UDI-PI (Production Identifier)" exactly. |
| Quantity of device (FLD-UDID-151) | 1 | Approved | Exact column match, approved in a bulk review | 100% | Column "Menge" matched "Quantity of device" exactly. |
| Certificate Type (FLD-UDID-60) | MDR type examination (MDR_TYPE_EXAMINATION) | Approved | Exact column match, approved in a bulk review | 100% | Column "Zertifikattyp" matched "Certificate Type" exactly. |
| Certificate Number (FLD-UDID-61) | 0123/2022/045678 | Approved | Exact column match, approved in a bulk review | 100% | Column "Zertifikatsnummer" matched "Certificate Number" exactly. |
| Notified Body (Certificate) (FLD-UDID-63) | 0123 | Approved | Exact column match, approved in a bulk review | 100% | Column "Benannte Stelle" matched "Notified Body (Certificate)" exactly. |
| Certificate Expiry Date (FLD-UDID-64) | 2027-04-30 | Approved | Exact column match, approved in a bulk review | 100% | Column "Ablaufdatum Zertifikat" matched "Certificate Expiry Date" exactly. |
| Member State where device is available (FLD-UDID-252) | DE,AT,FR,IT,ES,NL,BE,PL | Approved | Exact column match, approved in a bulk review | 100% | Column "Vertriebsland" matched "Member State where device is available" exactly. |
| Basic UDI-DI code (FLD-UDID-14) | 401161600010X5 | Approved | Column match after normalising the name, approved in a bulk review | 95% | Column "Basic-UDI-DI" matched "Basic UDI-DI code" after normalising punctuation/case. |

| Field | Value | Status | Source | Confidence | Reasoning |
|---|---|---|---|---|---|
| Substance - human blood or plasma derived (FLD-UDID-155) | false | Approved | AI column mapping, approved in a bulk review | 95% | AI mapped column "Blut- oder Plasmaderivat" to "Substance - human blood or plasma derived" (confidence 0.95). German for human blood or plasma derived substance |
| Market Info Start date (FLD-UDID-250) | 2023-06-15 | Approved | AI column mapping, approved in a bulk review | 90% | AI mapped column "Marktverfügbarkeit ab" to "Market Info Start date" (confidence 0.90). Complements mapped Member State availability |
| Issuing Entity Basic UDI-DI (FLD-UDID-01) | GS1 | Approved | Derived by rule, approved in a bulk review | 100% | Inferred from Basic UDI-DI code format, "401161600010X5" is a GS1 identifier. |
| Issuing Entity UDI-DI (FLD-UDID-291) | GS1 | Approved | Derived by rule, approved in a bulk review | 100% | Inferred from UDI-DI code format, "04011616010112" is a GS1 identifier. |
| System/Procedure Pack Type (FLD-UDID-12) | DEVICE | Approved | Declared by the customer, approved in a bulk review | 100% | Declared at project level by the project owner: every device in this project is a device in itself, not a system or a procedure pack (MDR Art. 22). EUDAMED field FLD-UDID-12. |
| Member State of first placing on EU market (FLD-UDID-137) | DE | Approved | Declared by the customer, approved in a bulk review | 100% | Declared at project level by the project owner: the devices in this project were first placed on the EU market in DE. EUDAMED field FLD-UDID-137. |
| Nomenclature code (EMDN) (FLD-UDID-149) | P090804010201 (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH FIXED NECK, STRAIGHT) | Approved | AI suggestion, approved by reviewer | 65% | The description's own words did not point to P090804010201. Similar devices registered in EUDAMED use this code (5 manufacturers, 334 registrations, 22% of filings, registered name similar in meaning to "quill pdo quill pdo polydioxanone"). Same product family, USP 3-0. A second check by another model could not be completed, so the first answer is shown. |
| Maximum number of reuses (FLD-UDID-157) | 0 | Approved | Derived by rule, approved by reviewer | 100% | Derived: device is labelled single use (FLD-UDID-167 = true), so maximum reuses is 0. |

| Field | Value | Status | Source | Confidence | Reasoning |
|---|---|---|---|---|---|
| Sterilisation method (FLD-UDID-165) | ETO | Approved | Exact column match, approved in a bulk review | 100% | Column "Sterilisationsverfahren" matched "Sterilisation method" exactly. |

## 4. Human Overrides

No override by a reviewer was recorded. Section 4.1 lists every recorded change to this device, including approvals and other edits.

## 4.1 Change history

The device was imported at 2026-10-08 21:38:58 UTC with 38 fields (event #58). Each line is one recorded change, oldest first. The event number is its position in this project's audit trail.

**Nomenclature code (EMDN) (FLD-UDID-149)**

- 2026-10-08 21:39:00 UTC. The AI classifier, run by ra.manager@beispiel-medizintechnik.de, set a new suggestion. (empty) -> "P090804010201" (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH FIXED NECK, STRAIGHT). Event #60.
- 2026-10-08 21:39:42 UTC. ra.manager@beispiel-medizintechnik.de approved "P090804010201" (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH FIXED NECK, STRAIGHT). The AI had suggested "P090804010201" (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH FIXED NECK, STRAIGHT) with 65% confidence in event #59. Event #102.

**Maximum number of reuses (FLD-UDID-157)**

- 2026-10-08 21:39:00 UTC. The AI classifier, run by ra.manager@beispiel-medizintechnik.de, set a new suggestion. (empty) -> "0". Event #60.
- 2026-10-08 21:39:43 UTC. ra.manager@beispiel-medizintechnik.de approved "0". Event #103.

**Device Name (FLD-UDID-22)**

- 2026-10-08 21:39:17 UTC. ra.manager@beispiel-medizintechnik.de approved "Zementfreier Hüftschaft Größe 11" in bulk review B-07A2C765. Event #77.

**Applicable Legislation (FLD-UDID-11)**

- 2026-10-08 21:39:17 UTC. ra.manager@beispiel-medizintechnik.de approved "MDR" in bulk review B-07A2C765. Event #77.

**Risk Class (FLD-UDID-16)**

- 2026-10-08 21:39:17 UTC. ra.manager@beispiel-medizintechnik.de approved "CLASS_III" in bulk review B-07A2C765. Event #77.

**Legal Manufacturer SRN (FLD-UDID-10)**

- 2026-10-08 21:39:17 UTC. ra.manager@beispiel-medizintechnik.de approved "DE-MF-000000042" in bulk review B-07A2C765. Event #77.

**Implantable (FLD-UDID-30)**

- 2026-10-08 21:39:17 UTC. ra.manager@beispiel-medizintechnik.de approved "true" in bulk review B-07A2C765. Event #77.

**Active Device (FLD-UDID-28)**

- 2026-10-08 21:39:17 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #77.

**Measuring Function (FLD-UDID-31)**

- 2026-10-08 21:39:17 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #77.

**Reusable Surgical Instruments (FLD-UDID-32)**

- 2026-10-08 21:39:17 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #77.

**Presence of animal tissues or cells (FLD-UDID-18)**

- 2026-10-08 21:39:17 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #77.

**Presence of human tissues or cells (FLD-UDID-23)**

- 2026-10-08 21:39:17 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #77.

**Device intended to administer medicinal product (FLD-UDID-29)**

- 2026-10-08 21:39:17 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #77.

**Substance - may be considered medicinal product (FLD-UDID-158)**

- 2026-10-08 21:39:17 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #77.

**Reference / Catalogue number (FLD-UDID-163)**

- 2026-10-08 21:39:17 UTC. ra.manager@beispiel-medizintechnik.de approved "ART-1011" in bulk review B-07A2C765. Event #77.

**Trade name (FLD-UDID-176)**

- 2026-10-08 21:39:17 UTC. ra.manager@beispiel-medizintechnik.de approved "DE: OrthoFlex Hip Stem Größe 11" in bulk review B-07A2C765. Event #77.

**UDI-DI code (FLD-UDID-178)**

- 2026-10-08 21:39:17 UTC. ra.manager@beispiel-medizintechnik.de approved "04011616010112" in bulk review B-07A2C765. Event #77.

**Device labelled sterile (FLD-UDID-169)**

- 2026-10-08 21:39:17 UTC. ra.manager@beispiel-medizintechnik.de approved "true" in bulk review B-07A2C765. Event #77.

**Need for sterilisation before use (FLD-UDID-170)**

- 2026-10-08 21:39:17 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #77.

**Labelled as single use (FLD-UDID-167)**

- 2026-10-08 21:39:17 UTC. ra.manager@beispiel-medizintechnik.de approved "true" in bulk review B-07A2C765. Event #77.

**Reprocessed single use device (FLD-UDID-164)**

- 2026-10-08 21:39:17 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #77.

**Containing latex (FLD-UDID-156)**

- 2026-10-08 21:39:17 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #77.

**Device Status (FLD-UDID-130)**

- 2026-10-08 21:39:17 UTC. ra.manager@beispiel-medizintechnik.de approved "ON_THE_MARKET" in bulk review B-07A2C765. Event #77.

**Type of UDI-PI (Production Identifier) (FLD-UDID-148)**

- 2026-10-08 21:39:17 UTC. ra.manager@beispiel-medizintechnik.de approved "SERIALISATION_NUMBER" in bulk review B-07A2C765. Event #77.

**Quantity of device (FLD-UDID-151)**

- 2026-10-08 21:39:17 UTC. ra.manager@beispiel-medizintechnik.de approved "1" in bulk review B-07A2C765. Event #77.

**Certificate Type (FLD-UDID-60)**

- 2026-10-08 21:39:17 UTC. ra.manager@beispiel-medizintechnik.de approved "MDR_TYPE_EXAMINATION" in bulk review B-07A2C765. Event #77.

**Certificate Number (FLD-UDID-61)**

- 2026-10-08 21:39:17 UTC. ra.manager@beispiel-medizintechnik.de approved "0123/2022/045678" in bulk review B-07A2C765. Event #77.

**Notified Body (Certificate) (FLD-UDID-63)**

- 2026-10-08 21:39:17 UTC. ra.manager@beispiel-medizintechnik.de approved "0123" in bulk review B-07A2C765. Event #77.

**Certificate Expiry Date (FLD-UDID-64)**

- 2026-10-08 21:39:17 UTC. ra.manager@beispiel-medizintechnik.de approved "2027-04-30" in bulk review B-07A2C765. Event #77.

**Member State where device is available (FLD-UDID-252)**

- 2026-10-08 21:39:17 UTC. ra.manager@beispiel-medizintechnik.de approved "DE,AT,FR,IT,ES,NL,BE,PL" in bulk review B-07A2C765. Event #77.

**Basic UDI-DI code (FLD-UDID-14)**

- 2026-10-08 21:39:17 UTC. ra.manager@beispiel-medizintechnik.de approved "401161600010X5" in bulk review B-07A2C765. Event #77.

**Substance - human blood or plasma derived (FLD-UDID-155)**

- 2026-10-08 21:39:17 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #77.

**Market Info Start date (FLD-UDID-250)**

- 2026-10-08 21:39:17 UTC. ra.manager@beispiel-medizintechnik.de approved "2023-06-15" in bulk review B-07A2C765. Event #77.

**Issuing Entity Basic UDI-DI (FLD-UDID-01)**

- 2026-10-08 21:39:17 UTC. ra.manager@beispiel-medizintechnik.de approved "GS1" in bulk review B-07A2C765. Event #77.

**Issuing Entity UDI-DI (FLD-UDID-291)**

- 2026-10-08 21:39:17 UTC. ra.manager@beispiel-medizintechnik.de approved "GS1" in bulk review B-07A2C765. Event #77.

**System/Procedure Pack Type (FLD-UDID-12)**

- 2026-10-08 21:39:17 UTC. ra.manager@beispiel-medizintechnik.de approved "DEVICE" in bulk review B-07A2C765. Event #77.

**Member State of first placing on EU market (FLD-UDID-137)**

- 2026-10-08 21:39:17 UTC. ra.manager@beispiel-medizintechnik.de approved "DE" in bulk review B-07A2C765. Event #77.

**Sterilisation method (FLD-UDID-165)**

- 2026-10-08 21:39:17 UTC. ra.manager@beispiel-medizintechnik.de approved "ETO" in bulk review B-07A2C765. Event #77.

## 5. Validation History

- At upload, 2026-10-08 21:38:03 UTC. The rule check found 1 error(s) for this device
  - Error BR-MANDATORY, FLD-UDID-149. The rule check reported "Mandatory field missing for MDR".
- At export, 2026-10-08 21:40:08 UTC. 0 error(s), 0 warning(s) for this device under MDR
  - Language of a text. Trade name (FLD-UDID-176) is DE. The language code was written before the text in the uploaded file.
  - Passed EUDAMED's XSD format check.
- **Final status:** PASSED at export (2026-10-08 21:40:08 UTC). No rule errors, 0 warning(s), XSD check passed.

## 6. Milestones

- **Snapshot at upload** by ra.manager@beispiel-medizintechnik.de at 2026-10-08 21:38:57 UTC
- **Snapshot at export** by ra.manager@beispiel-medizintechnik.de at 2026-10-08 21:40:09 UTC

## 7. Full Timeline

- 2026-10-08 21:38:01 UTC. **File uploaded.** sample_catalogue.csv, 14 rows
- 2026-10-08 21:38:02 UTC. **Columns mapped.** 38 of 40 columns mapped (95%)
- 2026-10-08 21:38:03 UTC. **Validation at upload.** 1 error(s) for this device
- 2026-10-08 21:38:56 UTC. **Legislation determined.** MDR, stated in the uploaded file (FLD-UDID-11 as supplied (MDR))
- 2026-10-08 21:38:57 UTC. **Snapshot.** Snapshot at upload, by ra.manager@beispiel-medizintechnik.de
- 2026-10-08 21:38:58 UTC. **Device imported.** 38 fields imported, event #58
- 2026-10-08 21:38:59 UTC. **AI EMDN suggestion.** AI suggested P090804010201 (65% confidence)
- 2026-10-08 21:39:00 UTC. **Field change.** 2 field change(s) by the AI classifier, event #60
- 2026-10-08 21:39:17 UTC. **Field change.** 36 field change(s) by ra.manager@beispiel-medizintechnik.de, event #77
- 2026-10-08 21:39:42 UTC. **Field change.** 1 field change(s) by ra.manager@beispiel-medizintechnik.de, event #102
- 2026-10-08 21:39:43 UTC. **Field change.** 1 field change(s) by ra.manager@beispiel-medizintechnik.de, event #103
- 2026-10-08 21:40:08 UTC. **Validation at export.** 0 error(s), 0 warning(s). XSD check passed
- 2026-10-08 21:40:09 UTC. **Snapshot.** Snapshot at export, by ra.manager@beispiel-medizintechnik.de

# Device ART-1012, UDI-DI 04011616010129, "Zementfreier Hüftschaft Größe 12"

**Reference number:** ART-1012
**Device UDI-DI:** 04011616010129
**Name:** Zementfreier Hüftschaft Größe 12
**Legislation:** MDR, stated in the uploaded file
**Reviewed by:** ra.manager@beispiel-medizintechnik.de on 2026-10-08 21:39:45 UTC
**Events in this record:** 13

## 1. Data Provenance

- **sample_catalogue.csv** (csv, 14 rows), uploaded 2026-10-08 21:38:01 UTC

## 2. Column Mapping

- Mapped: 38 of 40 columns (95%)
- By method: exact match 33, normalised name 1, alias 0, AI 4
- Mandatory fields with no source column at upload: Nomenclature code (EMDN)

## 3. EMDN Classification

- **Confirmed by reviewer, the AI suggestion:** P090804010202 (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH FIXED NECK, ANATOMICAL), AI confidence 90%
  - AI reasoning: Description states 'zementfrei' (uncemented) and 'Hüftschaft' (hip stem), so the code is supported. Neck type is not stated. A second check by another model could not be completed, so the first answer is shown.
  - Other codes listed for comparison. Their search match is not the confidence printed above. P090804010201 (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH FIXED NECK, STRAIGHT) (search match 19%); P090804010206 (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH MODULAR NECK, STRAIGHT) (search match 65%); P090804010207 (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH MODULAR NECK, ANATOMICAL) (search match 65%); P090804030201 (REVISION UNCEMENTED FEMORAL STEMS, WITH FIXED NECK) (search match 62%)

## 3.5 Field-Level Reasoning

Each value below shows the source column, rule, reviewer action or AI rationale that produced it.

| Field | Value | Status | Source | Confidence | Reasoning |
|---|---|---|---|---|---|
| Device Name (FLD-UDID-22) | Zementfreier Hüftschaft Größe 12 | Approved | Exact column match, approved in a bulk review | 100% | Column "Bezeichnung" matched "Device Name" exactly. |
| Applicable Legislation (FLD-UDID-11) | MDR | Approved | Exact column match, approved in a bulk review | 100% | Column "Rechtsgrundlage" matched "Applicable Legislation" exactly. |

| Field | Value | Status | Source | Confidence | Reasoning |
|---|---|---|---|---|---|
| Risk Class (FLD-UDID-16) | Class III (CLASS_III) | Approved | Exact column match, approved in a bulk review | 100% | Column "Risikoklasse" matched "Risk Class" exactly. |
| Legal Manufacturer SRN (FLD-UDID-10) | DE-MF-000000042 | Approved | Exact column match, approved in a bulk review | 100% | Column "Hersteller-SRN" matched "Legal Manufacturer SRN" exactly. |
| Implantable (FLD-UDID-30) | true | Approved | Exact column match, approved in a bulk review | 100% | Column "Implantierbar" matched "Implantable" exactly. |
| Active Device (FLD-UDID-28) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Aktives Medizinprodukt" matched "Active Device" exactly. |
| Measuring Function (FLD-UDID-31) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Messfunktion" matched "Measuring Function" exactly. |
| Reusable Surgical Instruments (FLD-UDID-32) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Wiederverwendbar" matched "Reusable Surgical Instruments" exactly. |
| Presence of animal tissues or cells (FLD-UDID-18) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Tierisches Gewebe" matched "Presence of animal tissues or cells" exactly. |
| Presence of human tissues or cells (FLD-UDID-23) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Menschliches Gewebe" matched "Presence of human tissues or cells" exactly. |
| Device intended to administer medicinal product (FLD-UDID-29) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Arzneimittelabgabe" matched "Device intended to administer medicinal product" exactly. |
| Substance - may be considered medicinal product (FLD-UDID-158) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Arzneimittel" matched "Substance - may be considered medicinal product" exactly. |
| Reference / Catalogue number (FLD-UDID-163) | ART-1012 | Approved | Exact column match, approved in a bulk review | 100% | Column "Artikelnummer" matched "Reference / Catalogue number" exactly. |
| Trade name (FLD-UDID-176) | DE: OrthoFlex Hip Stem Größe 12 | Approved | Exact column match, approved in a bulk review | 100% | Column "Handelsname" matched "Trade name" exactly. |
| UDI-DI code (FLD-UDID-178) | 04011616010129 | Approved | Exact column match, approved in a bulk review | 100% | Column "GTIN" matched "UDI-DI code" exactly. |
| Device labelled sterile (FLD-UDID-169) | true | Approved | Exact column match, approved in a bulk review | 100% | Column "Steril" matched "Device labelled sterile" exactly. |

| Field | Value | Status | Source | Confidence | Reasoning |
|---|---|---|---|---|---|
| Need for sterilisation before use (FLD-UDID-170) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Sterilisation" matched "Need for sterilisation before use" exactly. |
| Labelled as single use (FLD-UDID-167) | true | Approved | Exact column match, approved in a bulk review | 100% | Column "Einmalgebrauch" matched "Labelled as single use" exactly. |
| Reprocessed single use device (FLD-UDID-164) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Aufbereitet" matched "Reprocessed single use device" exactly. |
| Containing latex (FLD-UDID-156) | false | Approved | Exact column match, approved in a bulk review | 100% | Column "Enthält Latex" matched "Containing latex" exactly. |
| Device Status (FLD-UDID-130) | On the market (ON_THE_MARKET) | Approved | Exact column match, approved in a bulk review | 100% | Column "Marktstatus" matched "Device Status" exactly. |
| Type of UDI-PI (Production Identifier) (FLD-UDID-148) | Serialisation number (SERIALISATION_NUMBER) | Approved | Exact column match, approved in a bulk review | 100% | Column "UDI-PI Typ" matched "Type of UDI-PI (Production Identifier)" exactly. |
| Quantity of device (FLD-UDID-151) | 1 | Approved | Exact column match, approved in a bulk review | 100% | Column "Menge" matched "Quantity of device" exactly. |
| Certificate Type (FLD-UDID-60) | MDR type examination (MDR_TYPE_EXAMINATION) | Approved | Exact column match, approved in a bulk review | 100% | Column "Zertifikattyp" matched "Certificate Type" exactly. |
| Certificate Number (FLD-UDID-61) | 0123/2022/045678 | Approved | Exact column match, approved in a bulk review | 100% | Column "Zertifikatsnummer" matched "Certificate Number" exactly. |
| Notified Body (Certificate) (FLD-UDID-63) | 0123 | Approved | Exact column match, approved in a bulk review | 100% | Column "Benannte Stelle" matched "Notified Body (Certificate)" exactly. |
| Certificate Expiry Date (FLD-UDID-64) | 2027-04-30 | Approved | Exact column match, approved in a bulk review | 100% | Column "Ablaufdatum Zertifikat" matched "Certificate Expiry Date" exactly. |
| Member State where device is available (FLD-UDID-252) | DE,AT,FR,IT,ES,NL,BE,PL | Approved | Exact column match, approved in a bulk review | 100% | Column "Vertriebsland" matched "Member State where device is available" exactly. |
| Basic UDI-DI code (FLD-UDID-14) | 401161600010X5 | Approved | Column match after normalising the name, approved in a bulk review | 95% | Column "Basic-UDI-DI" matched "Basic UDI-DI code" after normalising punctuation/case. |
| Substance - human blood or plasma derived (FLD-UDID-155) | false | Approved | AI column mapping, approved in a bulk review | 95% | AI mapped column "Blut- oder Plasmaderivat" to "Substance - human blood or plasma derived" (confidence 0.95). German for human blood or plasma derived substance |

| Field | Value | Status | Source | Confidence | Reasoning |
|---|---|---|---|---|---|
| Market Info Start date (FLD-UDID-250) | 2023-06-15 | Approved | AI column mapping, approved in a bulk review | 90% | AI mapped column "Marktverfügbarkeit ab" to "Market Info Start date" (confidence 0.90). Complements mapped Member State availability |
| Issuing Entity Basic UDI-DI (FLD-UDID-01) | GS1 | Approved | Derived by rule, approved in a bulk review | 100% | Inferred from Basic UDI-DI code format, "401161600010X5" is a GS1 identifier. |
| Issuing Entity UDI-DI (FLD-UDID-291) | GS1 | Approved | Derived by rule, approved in a bulk review | 100% | Inferred from UDI-DI code format, "04011616010129" is a GS1 identifier. |
| System/Procedure Pack Type (FLD-UDID-12) | DEVICE | Approved | Declared by the customer, approved in a bulk review | 100% | Declared at project level by the project owner: every device in this project is a device in itself, not a system or a procedure pack (MDR Art. 22). EUDAMED field FLD-UDID-12. |
| Member State of first placing on EU market (FLD-UDID-137) | DE | Approved | Declared by the customer, approved in a bulk review | 100% | Declared at project level by the project owner: the devices in this project were first placed on the EU market in DE. EUDAMED field FLD-UDID-137. |
| Nomenclature code (EMDN) (FLD-UDID-149) | P090804010202 (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH FIXED NECK, ANATOMICAL) | Approved | AI suggestion, approved by reviewer | 90% | Description states 'zementfrei' (uncemented) and 'Hüftschaft' (hip stem), so the code is supported. Neck type is not stated. A second check by another model could not be completed, so the first answer is shown. |
| Maximum number of reuses (FLD-UDID-157) | 0 | Approved | Derived by rule, approved by reviewer | 100% | Derived: device is labelled single use (FLD-UDID-167 = true), so maximum reuses is 0. |
| Sterilisation method (FLD-UDID-165) | ETO | Approved | Exact column match, approved in a bulk review | 100% | Column "Sterilisationsverfahren" matched "Sterilisation method" exactly. |

## 4. Human Overrides

No override by a reviewer was recorded. Section 4.1 lists every recorded change to this device, including approvals and other edits.

## 4.1 Change history

The device was imported at 2026-10-08 21:39:03 UTC with 38 fields (event #63). Each line is one recorded change, oldest first. The event number is its position in this project's audit trail.

**Nomenclature code (EMDN) (FLD-UDID-149)**

- 2026-10-08 21:39:05 UTC. The AI classifier, run by ra.manager@beispiel-medizintechnik.de, set a new suggestion. (empty) -> "P090804010202" (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH FIXED NECK, ANATOMICAL). Event #65.
- 2026-10-08 21:39:44 UTC. ra.manager@beispiel-medizintechnik.de approved "P090804010202" (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH FIXED NECK, ANATOMICAL). The AI had suggested "P090804010202" (UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH FIXED NECK, ANATOMICAL) with 90% confidence in event #64. Event #104.

**Maximum number of reuses (FLD-UDID-157)**

- 2026-10-08 21:39:05 UTC. The AI classifier, run by ra.manager@beispiel-medizintechnik.de, set a new suggestion. (empty) -> "0". Event #65.
- 2026-10-08 21:39:45 UTC. ra.manager@beispiel-medizintechnik.de approved "0". Event #105.

**Device Name (FLD-UDID-22)**

- 2026-10-08 21:39:18 UTC. ra.manager@beispiel-medizintechnik.de approved "Zementfreier Hüftschaft Größe 12" in bulk review B-07A2C765. Event #78.

**Applicable Legislation (FLD-UDID-11)**

- 2026-10-08 21:39:18 UTC. ra.manager@beispiel-medizintechnik.de approved "MDR" in bulk review B-07A2C765. Event #78.

**Risk Class (FLD-UDID-16)**

- 2026-10-08 21:39:18 UTC. ra.manager@beispiel-medizintechnik.de approved "CLASS_III" in bulk review B-07A2C765. Event #78.

**Legal Manufacturer SRN (FLD-UDID-10)**

- 2026-10-08 21:39:18 UTC. ra.manager@beispiel-medizintechnik.de approved "DE-MF-000000042" in bulk review B-07A2C765. Event #78.

**Implantable (FLD-UDID-30)**

- 2026-10-08 21:39:18 UTC. ra.manager@beispiel-medizintechnik.de approved "true" in bulk review B-07A2C765. Event #78.

**Active Device (FLD-UDID-28)**

- 2026-10-08 21:39:18 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #78.

**Measuring Function (FLD-UDID-31)**

- 2026-10-08 21:39:18 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #78.

**Reusable Surgical Instruments (FLD-UDID-32)**

- 2026-10-08 21:39:18 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #78.

**Presence of animal tissues or cells (FLD-UDID-18)**

- 2026-10-08 21:39:18 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #78.

**Presence of human tissues or cells (FLD-UDID-23)**

- 2026-10-08 21:39:18 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #78.

**Device intended to administer medicinal product (FLD-UDID-29)**

- 2026-10-08 21:39:18 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #78.

**Substance - may be considered medicinal product (FLD-UDID-158)**

- 2026-10-08 21:39:18 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #78.

**Reference / Catalogue number (FLD-UDID-163)**

- 2026-10-08 21:39:18 UTC. ra.manager@beispiel-medizintechnik.de approved "ART-1012" in bulk review B-07A2C765. Event #78.

**Trade name (FLD-UDID-176)**

- 2026-10-08 21:39:18 UTC. ra.manager@beispiel-medizintechnik.de approved "DE: OrthoFlex Hip Stem Größe 12" in bulk review B-07A2C765. Event #78.

**UDI-DI code (FLD-UDID-178)**

- 2026-10-08 21:39:18 UTC. ra.manager@beispiel-medizintechnik.de approved "04011616010129" in bulk review B-07A2C765. Event #78.

**Device labelled sterile (FLD-UDID-169)**

- 2026-10-08 21:39:18 UTC. ra.manager@beispiel-medizintechnik.de approved "true" in bulk review B-07A2C765. Event #78.

**Need for sterilisation before use (FLD-UDID-170)**

- 2026-10-08 21:39:18 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #78.

**Labelled as single use (FLD-UDID-167)**

- 2026-10-08 21:39:18 UTC. ra.manager@beispiel-medizintechnik.de approved "true" in bulk review B-07A2C765. Event #78.

**Reprocessed single use device (FLD-UDID-164)**

- 2026-10-08 21:39:18 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #78.

**Containing latex (FLD-UDID-156)**

- 2026-10-08 21:39:18 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #78.

**Device Status (FLD-UDID-130)**

- 2026-10-08 21:39:18 UTC. ra.manager@beispiel-medizintechnik.de approved "ON_THE_MARKET" in bulk review B-07A2C765. Event #78.

**Type of UDI-PI (Production Identifier) (FLD-UDID-148)**

- 2026-10-08 21:39:18 UTC. ra.manager@beispiel-medizintechnik.de approved "SERIALISATION_NUMBER" in bulk review B-07A2C765. Event #78.

**Quantity of device (FLD-UDID-151)**

- 2026-10-08 21:39:18 UTC. ra.manager@beispiel-medizintechnik.de approved "1" in bulk review B-07A2C765. Event #78.

**Certificate Type (FLD-UDID-60)**

- 2026-10-08 21:39:18 UTC. ra.manager@beispiel-medizintechnik.de approved "MDR_TYPE_EXAMINATION" in bulk review B-07A2C765. Event #78.

**Certificate Number (FLD-UDID-61)**

- 2026-10-08 21:39:18 UTC. ra.manager@beispiel-medizintechnik.de approved "0123/2022/045678" in bulk review B-07A2C765. Event #78.

**Notified Body (Certificate) (FLD-UDID-63)**

- 2026-10-08 21:39:18 UTC. ra.manager@beispiel-medizintechnik.de approved "0123" in bulk review B-07A2C765. Event #78.

**Certificate Expiry Date (FLD-UDID-64)**

- 2026-10-08 21:39:18 UTC. ra.manager@beispiel-medizintechnik.de approved "2027-04-30" in bulk review B-07A2C765. Event #78.

**Member State where device is available (FLD-UDID-252)**

- 2026-10-08 21:39:18 UTC. ra.manager@beispiel-medizintechnik.de approved "DE,AT,FR,IT,ES,NL,BE,PL" in bulk review B-07A2C765. Event #78.

**Basic UDI-DI code (FLD-UDID-14)**

- 2026-10-08 21:39:18 UTC. ra.manager@beispiel-medizintechnik.de approved "401161600010X5" in bulk review B-07A2C765. Event #78.

**Substance - human blood or plasma derived (FLD-UDID-155)**

- 2026-10-08 21:39:18 UTC. ra.manager@beispiel-medizintechnik.de approved "false" in bulk review B-07A2C765. Event #78.

**Market Info Start date (FLD-UDID-250)**

- 2026-10-08 21:39:18 UTC. ra.manager@beispiel-medizintechnik.de approved "2023-06-15" in bulk review B-07A2C765. Event #78.

**Issuing Entity Basic UDI-DI (FLD-UDID-01)**

- 2026-10-08 21:39:18 UTC. ra.manager@beispiel-medizintechnik.de approved "GS1" in bulk review B-07A2C765. Event #78.

**Issuing Entity UDI-DI (FLD-UDID-291)**

- 2026-10-08 21:39:18 UTC. ra.manager@beispiel-medizintechnik.de approved "GS1" in bulk review B-07A2C765. Event #78.

**System/Procedure Pack Type (FLD-UDID-12)**

- 2026-10-08 21:39:18 UTC. ra.manager@beispiel-medizintechnik.de approved "DEVICE" in bulk review B-07A2C765. Event #78.

**Member State of first placing on EU market (FLD-UDID-137)**

- 2026-10-08 21:39:18 UTC. ra.manager@beispiel-medizintechnik.de approved "DE" in bulk review B-07A2C765. Event #78.

**Sterilisation method (FLD-UDID-165)**

- 2026-10-08 21:39:18 UTC. ra.manager@beispiel-medizintechnik.de approved "ETO" in bulk review B-07A2C765. Event #78.

## 5. Validation History

- At upload, 2026-10-08 21:38:03 UTC. The rule check found 1 error(s) for this device
  - Error BR-MANDATORY, FLD-UDID-149. The rule check reported "Mandatory field missing for MDR".
- At export, 2026-10-08 21:40:10 UTC. 0 error(s), 0 warning(s) for this device under MDR
  - Language of a text. Trade name (FLD-UDID-176) is DE. The language code was written before the text in the uploaded file.
  - Passed EUDAMED's XSD format check.
- **Final status:** PASSED at export (2026-10-08 21:40:10 UTC). No rule errors, 0 warning(s), XSD check passed.

## 6. Milestones

- **Snapshot at upload** by ra.manager@beispiel-medizintechnik.de at 2026-10-08 21:39:02 UTC
- **Snapshot at export** by ra.manager@beispiel-medizintechnik.de at 2026-10-08 21:40:11 UTC

## 7. Full Timeline

- 2026-10-08 21:38:01 UTC. **File uploaded.** sample_catalogue.csv, 14 rows
- 2026-10-08 21:38:02 UTC. **Columns mapped.** 38 of 40 columns mapped (95%)
- 2026-10-08 21:38:03 UTC. **Validation at upload.** 1 error(s) for this device
- 2026-10-08 21:39:01 UTC. **Legislation determined.** MDR, stated in the uploaded file (FLD-UDID-11 as supplied (MDR))
- 2026-10-08 21:39:02 UTC. **Snapshot.** Snapshot at upload, by ra.manager@beispiel-medizintechnik.de
- 2026-10-08 21:39:03 UTC. **Device imported.** 38 fields imported, event #63

- 2026-10-08 21:39:04 UTC. **AI EMDN suggestion.** AI suggested P090804010202 (90% confidence)
- 2026-10-08 21:39:05 UTC. **Field change.** 2 field change(s) by the AI classifier, event #65
- 2026-10-08 21:39:18 UTC. **Field change.** 36 field change(s) by ra.manager@beispiel-medizintechnik.de, event #78
- 2026-10-08 21:39:44 UTC. **Field change.** 1 field change(s) by ra.manager@beispiel-medizintechnik.de, event #104
- 2026-10-08 21:39:45 UTC. **Field change.** 1 field change(s) by ra.manager@beispiel-medizintechnik.de, event #105
- 2026-10-08 21:40:10 UTC. **Validation at export.** 0 error(s), 0 warning(s). XSD check passed
- 2026-10-08 21:40:11 UTC. **Snapshot.** Snapshot at export, by ra.manager@beispiel-medizintechnik.de

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Registration Decision Record, format version 2.0, generated by EUDAMate