Registration Decision Record

Project: sample_catalogue.csv
Project ID: proj-1
Legislation: MDR (12 devices)
Devices: 12
Generated: 2026-10-19 16:52:33 UTC
Generated by: ra.manager@beispiel-medizintechnik.de
Record format version: 1.1

All times in this record are UTC.

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 04011616011043, "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 04011616011029, "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 04011616011064, "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 2026-10-19 16:52:33 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 04011616011015, "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 04011616011022, "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 04011616011036, "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	04011616011001	Zementfreier Hüftschaft Größe 1	MDR	Passed
ART-1002	04011616011008	Zementfreier Hüftschaft Größe 2	MDR	Passed
ART-1003	04011616011015	Zementfreier Hüftschaft Größe 3	MDR	Passed
ART-1004	04011616011022	Zementfreier Hüftschaft Größe 4	MDR	Passed
ART-1005	04011616011029	Zementfreier Hüftschaft Größe 5	MDR	Passed
ART-1006	04011616011036	Zementfreier Hüftschaft Größe 6	MDR	Passed
ART-1007	04011616011043	Zementfreier Hüftschaft Größe 7	MDR	Not passed
ART-1008	04011616011050	Zementfreier Hüftschaft Größe 8	MDR	Passed
ART-1009	04011616011057	Zementfreier Hüftschaft Größe 9	MDR	Passed
ART-1010	04011616011064	Zementfreier Hüftschaft Größe 10	MDR	Passed
ART-1011	04011616011071	Zementfreier Hüftschaft Größe 11	MDR	Passed
ART-1012	04011616011078	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 04011616011085, "Entferntes Gerät 1". Event #106.
- 2026-10-08 21:39:47 UTC. ra.manager@beispiel-medizintechnik.de removed the device ART-2002, UDI-DI 04011616011092, "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 aff8fbb3e9bd0574e22ac04cb91d8dfebb7ebc10ba750b3d89cbfeebc66c0f64, 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 04011616011001, "Zementfreier Hüftschaft Größe 1"

Reference number: ART-1001
Device UDI-DI: 04011616011001
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 the classifier listed. 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)	04011616011001	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)	4011616000106	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, "4011616000106" 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, "04011616011001" 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 'zemen tfrei' (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 "04011616011001" 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 "4011616000106" 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 04011616011008, "Zementfreier Hüftschaft Größe 2"

Reference number: ART-1002
Device UDI-DI: 04011616011008
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 the classifier listed. 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)	04011616011008	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)	4011616000106	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, "4011616000106" 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, "04011616011008" 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 "04011616011008" 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 "4011616000106" 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 04011616011015, "Zementfreier Hüftschaft Größe 3"

Reference number: ART-1003
Device UDI-DI: 04011616011015
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 the classifier listed. 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)	04011616011015	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)	4011616000106	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, "4011616000106" 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, "04011616011015" 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 'zemen tfrei' (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 "04011616011015" 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 "4011616000106" 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 04011616011022, "Zementfreier Hüftschaft Größe 4"

Reference number: ART-1004
Device UDI-DI: 04011616011022
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 the classifier listed. 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)	04011616011022	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)	4011616000106	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, "4011616000106" 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, "04011616011022" 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 'zeme ntfrei' (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 "04011616011022" 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 "4011616000106" 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 04011616011029, "Zementfreier Hüftschaft Größe 5"

Reference number: ART-1005
Device UDI-DI: 04011616011029
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 the classifier listed. 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)	04011616011029	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)	4011616000106	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, "4011616000106" 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, "04011616011029" 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 "04011616011029" 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 "4011616000106" 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 04011616011036, "Zementfreier Hüftschaft Größe 6"

Reference number: ART-1006
Device UDI-DI: 04011616011036
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 the classifier listed. 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)	04011616011036	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)	4011616000106	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, "4011616000106" 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, "04011616011036" 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 'zemen tfrei' (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 "04011616011036" 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 "4011616000106" 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 04011616011043, "Zementfreier Hüftschaft Größe 7"

Reference number: ART-1007
Device UDI-DI: 04011616011043
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 the classifier listed. 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)	04011616011043	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)	4011616000106	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, "4011616000106" 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, "04011616011043" 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 'zemen tfrei' (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 "04011616011043" 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 "4011616000106" 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 04011616011050, "Zementfreier Hüftschaft Größe 8"

Reference number: ART-1008
Device UDI-DI: 04011616011050
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 the classifier listed. 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)	04011616011050	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)	4011616000106	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, "4011616000106" 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, "04011616011050" 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 "04011616011050" 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 "4011616000106" 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 04011616011057, "Zementfreier Hüftschaft Größe 9"

Reference number: ART-1009
Device UDI-DI: 04011616011057
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 the classifier listed. 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)	04011616011057	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)	4011616000106	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, "4011616000106" 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, "04011616011057" 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 'zemen tfrei' (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 "04011616011057" 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 "4011616000106" 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 04011616011064, "Zementfreier Hüftschaft Größe 10"

Reference number: ART-1010
Device UDI-DI: 04011616011064
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 the classifier listed. 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)	04011616011064	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)	4011616000106	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, "4011616000106" 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, "04011616011064" 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 "04011616011064" 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 "4011616000106" 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 04011616011071, "Zementfreier Hüftschaft Größe 11"

Reference number: ART-1011
Device UDI-DI: 04011616011071
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 the classifier listed. 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)	04011616011071	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)	4011616000106	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, "4011616000106" 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, "04011616011071" 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 "04011616011071" 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 "4011616000106" 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 04011616011078, "Zementfreier Hüftschaft Größe 12"

Reference number: ART-1012
Device UDI-DI: 04011616011078
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 the classifier listed. 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)	04011616011078	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)	4011616000106	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, "4011616000106" 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, "04011616011078" 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 'zemen tfrei' (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 "04011616011078" 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 "4011616000106" 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 1.1, generated by EUDAMate