

Sample decision log

The process of a device file from data preparation to the technical response from EUDAMED

Sample with fictitious data. No real device, no real manufacturer, no real reviewer.

Musterprodukt Mullkompresse 10x10 cm, steril

Sample as of 26 October 2026

The sample file

Product name (unchanged)	Musterprodukt Mullkompresse 10x10 cm, steril
Manufacturer (unchanged)	Musterfirma Medizintechnik GmbH (sample manufacturer, placeholder)
SRN	DE-MF-000000000 (placeholder)
File	00000000-0000-4000-8000-000000000001
Basic UDI-DI	4099999MUSTER0001AB
UDI-DI	04099999000017
Risk class	Class Is, Rule 4, Annex VIII MDR (transferred from the manufacturer's classification)
EMDN code	M0201020101 (Cotton gauzes, folded, sterile)
Sterilisation method	STEAM
Placed on the market sterile	yes

The product name, manufacturer name, identifiers and technical codes are given unchanged, as in the record; identifiers and codes are set in monospace.

The process in five steps

No.	Step	Who	Result in the sample	Date
1	Data preparation	Medregia; confirmations by the manufacturer's team	Record with the source of each value, open questions resolved, 28 of 28 mandatory fields	1 to 3 September 2026
2	Expert review	The manufacturer's RA team, its consultant or an expert named in the proposal; in the sample: Dr. Beispiel (placeholder)	Review verdict: 5 of 5 check points reviewed, no objections	4 September 2026
3	Sign-off by the manufacturer	The manufacturer; in the sample: the sample manufacturer (placeholder)	Documented sign-off for submission	7 September 2026
4	XML submission	Medregia, in the manufacturer's own EUDAMED account	DEVICE.POST by XML bulk upload, one device	8 September 2026
5	Technical response from EUDAMED	EUDAMED	SUCCESS: technical acceptance, not regulatory approval by an authority	9 September 2026

- The expert review does not replace the manufacturer's sign-off. Nothing is submitted without the manufacturer's documented sign-off.
- Confirmations during preparation are not a sign-off.
- The technical response from EUDAMED is not regulatory approval by an authority. Regulatory responsibility remains with the manufacturer.

Step 1: Data preparation

Medregia transfers the details from the manufacturer's documents and records the source of each value. Missing or contradictory details are not guessed but resolved as open questions.

Fields of the sample file

Field	Value	Source document	Status
Basic UDI-DI	4099999MUSTER0001AB	The manufacturer's product list.	transferred
UDI-DI	04099999000017	The manufacturer's product list. The UDI-DI field is empty.	resolved
Risk class	Class Is, Rule 4, Annex VIII MDR	The manufacturer's device details: non-invasive device, contact with injured skin, placed on the market sterile.	transferred
EMDN code	M0201020101 (Cotton gauzes, folded, sterile)	The official EMDN nomenclature of the European Commission.	transferred
Intended purpose	from the instructions for use, revision 3	The manufacturer's instructions for use, revision 3.	transferred
Sterilisation method	STEAM	Pre-filled value E0. The manufacturer's validation report states steam sterilisation.	resolved
Placed on the market sterile	yes	Pre-filled value from the device details.	confirmed

Manufacturer's declaration

2 September 2026, 11:30 Legal framework MDR. Reprocessed single-use devices under Article 17 MDR: no.

Open questions resolved

Time	Field	Before	After	Reason
3 September 2026, 13:00	UDI-DI	empty	04099999000017	The identifier was missing from the product list and was added by the manufacturer's team.
3 September 2026, 13:00	Sterilisation method	E0	STEAM	Source data preferred: the validation report states steam sterilisation.

Confirmations by the manufacturer's team

3 September 2026, 13:05 Pre-filled values confirmed: Placed on the market sterile, first EU country. A confirmation, not a sign-off.

3 September 2026, 13:10 Details confirmed: 28 of 28 mandatory fields complete. A confirmation, not a sign-off.

Step 2: Expert review

Reviewing role	The manufacturer's RA team, its consultant or an expert named in the proposal
In the sample	Dr. Beispiel (placeholder, not a real person)
Date	4 September 2026, 09:15

Review verdict

No.	Check point	Checked	Remark
1	EMDN code confirmed against the official nomenclature.	yes	M0201020101 is the terminal level for sterile, folded gauze swabs.
2	Risk class and application of the rule under Annex VIII MDR confirmed.	yes	Rule 4, Annex VIII MDR, contact with injured skin, Class Is.
3	Intended purpose compared with the instructions for use.	yes	Intended purpose matches the instructions for use, rev. 3.
4	Mandatory fields complete or gaps resolved.	yes	All 28 mandatory fields filled in, evidence of sterilisation supplied subsequently.
5	German and English device descriptions reviewed.	yes	German and English device descriptions correct in language and content.

Conclusion in the sample: file complete, no objections. The reviewer is a placeholder. The review verdict is not a sign-off; the manufacturer then gives its documented sign-off.

Step 3: Sign-off by the manufacturer

Signed off by	Sample manufacturer, Musterfirma Medizintechnik GmbH (placeholder, not a real person or company)
Date	7 September 2026, 16:00
Subject	Record for UDI-DI 04099999000017 in the version reviewed on 4 September 2026
Statement	Signed off for submission to EUDAMED.

The sign-off is the manufacturer's own step. The expert's review verdict does not replace it, and Medregia does not sign off on the manufacturer's behalf.

Step 4: XML submission in the manufacturer's EUDAMED account

Date	8 September 2026, 08:00
Route	XML bulk upload (DEVICE.POST)
Account	The manufacturer's EUDAMED account, SRN DE-MF-0000000000 (placeholder)
File	DEVICE_POST_MUSTER.xml, one device (not published)

The downloadable sample XML (medregia-muster-device-post.xml) and the sample device list (medregia-muster-produktliste.csv) contain five other fictitious devices with the same placeholder SRN and GS1 prefix 4099999. They are not the submission of this file.

Step 5: Technical response from EUDAMED

Date	9 September 2026, 08:30
Response code	SUCCESS
Reference	UDI-DI 04099999000017

SUCCESS means that EUDAMED has technically accepted the data. It is not an assessment of the content and not regulatory approval by an authority.

Chain of events in the sample log

Every stage of the sample file is an event with a timestamp and the party involved. The order follows the process: data preparation, expert review, sign-off by the manufacturer, submission and the technical response from EUDAMED.

No.	Time	Event	Content	Party
1	1 September 2026, 10:00	File created	Transferred from the manufacturer's product list, with the source of each value recorded.	Medregia
2	1 September 2026, 10:00	Risk class transferred	Class Is under Rule 4, Annex VIII MDR, from the manufacturer's classification.	Medregia
3	1 September 2026, 10:00	EMDN code assigned	M0201020101 checked against the official nomenclature, candidates M0201020101 and M020102.	Medregia
4	2 September 2026, 11:30	Manufacturer's declaration	Legal framework MDR. Reprocessed single-use devices under Article 17 MDR: no.	Manufacturer
5	3 September 2026, 13:00	Open questions resolved	UDI-DI from empty to 040999999000017. Sterilisation method from E0 to STEAM; reason: the validation report states steam sterilisation.	Manufacturer
6	3 September 2026, 13:05	Pre-filled values confirmed	Placed on the market sterile, first EU country. A confirmation, not a sign-off.	Manufacturer
7	3 September 2026, 13:10	Details confirmed	28 of 28 mandatory fields complete. A confirmation, not a sign-off.	Manufacturer
8	4 September 2026, 09:15	Expert review	Dr. Beispiel (placeholder), 5 of 5 check points reviewed, no objections. The review verdict is not a sign-off.	Reviewer
9	7 September 2026, 16:00	Sign-off by the manufacturer	The sample manufacturer (placeholder) signs off the reviewed record for submission.	Manufacturer
10	8 September 2026, 08:00	Submitted to EUDAMED	XML bulk upload DEVICE_POST_MUSTER.xml in the manufacturer's EUDAMED account DE-MF-0000000000, one device.	Medregia
11	9 September 2026, 08:30	Technical response from EUDAMED	SUCCESS for 040999999000017. Technical acceptance, not regulatory approval by an authority.	EUDAMED

Confirmations by the manufacturer's team during preparation (events 6 and 7) are not a sign-off. The manufacturer gives its sign-off as a separate step after the expert review (event 9); the review verdict does not replace it.

Notes on this sample

- All details are fictitious. The device, manufacturer, identifiers and people are not real; SRN DE-MF-0000000000, Dr. Beispiel and the sample manufacturer are placeholders.
- The sample does not come from a real file. It therefore contains no verification key and no hash values; the 'Verify a decision log' function on medregia.eu cannot be tried out with it.
- This sample is not legal advice and does not replace any sign-off or approval. The proposal for a project states the exact deliverables.