

Technical Documentation File EU MDR

Use this file to assemble controlled device evidence in the definition order of Annex II followed by Annex III. Enter document references and evidence status; an empty record is an evidence gap, not a conformity conclusion. Regulatory applicability and release decisions belong to the authorized reviewers.

Complete bracketed fields with approved information. Duplicate modules and rows as needed; record the reason for any section marked not applicable.

Document [ID and revision] **Owner** [Role] **Scope** [Organization, site or product]

Effective date [Date] **Approval** [Controlled record] **Next review** [Date or trigger]

Device description and specification

Device identity		Controlled description	
Name intended purpose and users		[Exact labelling wording and source revision]	
Patients indications and contraindications		[Population and approved claims]	
Operating principle and novel features		[Description and supporting evidence]	
Classification and Basic UDI DI		[Class, rule, reviewed rationale and identifier]	
Previous or similar generations		[Comparison and supporting controlled reference]	
Variant or accessory	Configuration materials and specification		Evidence
[Identifier]	[Values, units and compatibility]		[Drawing, specification and revision]

Information supplied by the manufacturer

Supplied information	Controlled version and scope	Consistency review
[Label, IFU or implant card]	[Language, variant and document ID]	[Purpose, claims and revision check]
[Warning or residual-risk disclosure]	[Exact wording, signal word and location]	[Linked risk and review result]
[Promotional claim]	[Exact claim and channel]	[Evidence and labelling consistency]

Design and manufacturing information

Stage or process	Site supplier and controls	Controlled evidence
[Design stage]	[Design output and review gate]	[Record and revision]
[Manufacturing step]	[Site, subcontractor, parameters and control]	[Validation or verification reference]

General safety and performance requirements

Keep one record per requirement and retain the reviewer justification for applicability. Split large matrices by chapter.

Requirement and applicability	Method and cited specification	Evidence and review status
[GSPR ID; applicable or justified not applicable]	[Conformity method; standard or common specification and edition]	[Evidence ID, section, version and reviewer finding]
[GSPR ID]	[Method and exact reference]	[Evidence or open gap]

Benefit risk analysis and risk management

Risk management element	Controlled record and conclusion status
Plan scope and acceptability criteria	[Lifecycle phases, method and approved criteria]
Hazard hazardous situation and harm	[Risk ID, sequence of events and evidence]
Initial estimation	[Severity/probability method and source rating]
Control and verification	[Inherent design, protective measure or information; implementation and effectiveness evidence]
Residual risk and disclosure	[Recorded evaluation, disclosure and labelling reference]
Overall benefit risk evaluation	[Authorized conclusion and evidence; unresolved gaps]
Production feedback	[Inputs, review trigger and risk-file update]

Risk control traceability

Risk and control ID	Implementation evidence	Effectiveness evidence and status
[IDs]	[Design or process record]	[Test, criterion, result and reviewed conclusion]

Product verification and validation

Preclinical evidence record

Repeat by test area such as software, biocompatibility, packaging, performance or sterilization when applicable.

Test area and requirement	Method configuration and criterion	Result and conclusion
[Test ID, risk and requirement]	[Standard edition, device configuration, samples and exact acceptance criterion]	[Report, values, units, deviation and recorded conclusion]
[Not performed]	[Reviewed rationale and existing data relied on]	[Evidence limitations and decision]

Clinical evaluation record

Evaluation element	Controlled evidence
Plan and claims	[Intended purpose, benefits, outcome parameters and plan revision]
Data sources	[Investigations, literature or equivalence evidence and comparison]
Appraisal and analysis	[Methods, populations, endpoints, statistics and limitations]
Conclusions and gaps	[Recorded safety/performance/benefit-risk conclusion and unresolved evidence]
PMCF and clinical follow up	[Plan, activities, results and evaluation report references]
Public clinical summary	[Where applicable: controlled summary and consistency review]

Evidence cross reference

Claim or GSPR	Clinical or test evidence	Risk or labelling consistency
[Identifier]	[Report and section]	[Linked record and reviewer result]

Post market surveillance

Surveillance element	Plan or report record	
Device scope and objectives	[Devices, period and PMS plan reference]	
Data sources	[Complaints, vigilance, service, literature, registries, feedback or PMCF]	
Indicators and trend method	[Definition, threshold, unit, rationale and review frequency]	
Incident handling and communication	[Classification rules, decision authority and applicable reviewed obligations]	
Feedback to other files	[Risk, clinical evaluation and corrective-action links]	
PMS report or PSUR	[Applicable report type, period, version, findings and authorized conclusion]	
Surveillance finding	Assessment and linked action	Review evidence
[Source and signal]	[Risk or clinical impact; CAPA or update]	[Decision, owner and record]

Glossary

Term or abbreviation	Approved meaning	Defining source
[Term used in the file]	[Expansion or definition]	[Controlled source]

Technical file readiness review

- ☐ Device identity, intended purpose, warnings and claims agree across controlled records.
- ☐ Applicability decisions and conclusions have evidence; no blank result is marked as passed or conforming.
- ☐ Open risks, deviations and evidence gaps are visible to the release authority.

Reviewer function	Scope and decision	Date reference and open actions
[Regulatory, quality or technical role]	[Review scope; approved or returned]	[Controlled approval and gaps]