Chapter 9 Template: Technical Documentation Architecture & Traceability Matrix

Subtract to Ship: MDR Certification, Chapter 9: Technical Documentation*

Instructions

Build the skeleton first, then fill it. This template gives you the Annex II folder structure, the document ID system, and the traceability matrix format. Follow Annex II structure exactly, do not invent your own. An auditor who finds Annex II sections in Annex II order knows where everything is before they start reading.

Part 1: Folder Structure (Annex II)

Create this structure in your document management system:

``` 01-Device-Description-and-Specification/ DD-001 Device Description DD-002 Intended Purpose Statement DD-003 Variants and Accessories DD-004 Bill of Materials DD-005 UDI Information

02-Information-Supplied-by-Manufacturer/ IS-001 Labels (all variants) IS-002 Instructions for Use IS-003 Packaging Information

03-Design-and-Manufacturing/ DM-001 Design and Development Plan DM-002 Design Input Requirements DM-003 Design Output Specifications DM-004 Manufacturing Process Description DM-005 Supplier Qualification Records

04-GSPR-Compliance/ GC-001 GSPR Checklist (Annex I mapping) GC-002 Applied Standards List

05-Risk-Management/ RM-001 Risk Management Plan RM-002 Risk Management Report RM-003 Benefit-Risk Analysis

06-Product-Verification-and-Validation/ VV-001 Verification Plan VV-002 Verification Reports (by test type) VV-003 Validation Plan VV-004 Validation Reports VV-005 Clinical Evaluation Report

07-Post-Market-Surveillance/ PM-001 PMS Plan PM-002 PMCF Plan (if applicable) PM-003 PMS Report / PSUR template ```

**Document ID convention:** Type abbreviation + sequential number + version (e.g., RM-001-v2)
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Part 2: Seven Themes Checklist

For each theme, note the current status:

Theme	Description	Documents Created?	Content Complete?
1	Device description and specification	Yes No	Yes No
2	Information supplied by manufacturer (labels, IFU)	Yes No	Yes No
3	Design and manufacturing information	Yes No	Yes No
4	GSPR compliance (Annex I mapping)	Yes No	Yes No
5	Benefit-risk analysis and risk management	Yes No	Yes No
6	Product verification and validation	Yes No	Yes No
7	Post-market surveillance	Yes No	Yes No

Part 3: Traceability Matrix

Build this early. Update it constantly. This is the map that prevents treasure hunts.

Req ID	Requirement Source	Requirement Description	Design Output Ref	Verification Evidence	Risk Reference
REQ-001					
REQ-002					
REQ-003					
REQ-004					
REQ-005					
REQ-006					
REQ-007					
REQ-008					

Part 4: GSPR Checklist Template (Annex I)

For EVERY requirement in Annex I, make a deliberate decision:

GSPR #	Requirement	Applicable?	Evidence Document ID	Section	Notes
1	General requirement, devices shall achieve performance intended	Yes N/A			
2	General requirement, state of the art	Yes N/A			
3	Risk management	Yes N/A			
...	...				
10.1	Biocompatibility	Yes N/A			
...	...				
14	Electronic programmable systems	Yes N/A			
...	...				
17.2	Personal data processing	Yes N/A			
...	...				
23	Label and IFU requirements	Yes N/A			

If "N/A": Write one sentence explaining why. The auditor needs to see you considered it.

Part 5: Intended Purpose Consistency Check

Your intended purpose must read **identically** in all of these documents:

Document	Intended Purpose Matches DD-002?
Device Description (DD-001)	Yes No
Clinical Evaluation Report (VV-005)	Yes No
Risk Management Report (RM-002)	Yes No
Labels (IS-001)	Yes No
Instructions for Use (IS-002)	Yes No
Website / marketing materials	Yes No

Any "No" is a nonconformity waiting to be found.

Part 6: Five-Question Document Review

Before submitting any document to the NB, it must pass all five:

#	Question	Pass?
1	Does this document have a unique ID, version number, and approval signature?	
2	Does every claim trace to evidence in another document?	
3	Does the intended purpose match DD-002 word for word?	
4	Could this be shorter without losing information?	
5	If I removed this document, would there be a gap in the GSPR checklist?	

Date completed:

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Completed by:

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