



EU MDR Technical File Starter Kit

Organize an EU MDR technical file, GSPR evidence and post-market surveillance.

What's inside

File	What it is / how to use it
01_Technical_Documentation_Starter.docx	Annex II/III section index, classification rationale, DoC checklist.
02_GSPR_Checklist_and_PMS_Data_Log.xlsx	23 GSPR topics (paraphrased) with applicability, method, evidence and flags; PMS data log with complaint rate.
03_PMS_Plan_and_Psur_Templates.docx	PMS plan elements, PMS report / PSUR sections.

Templates, not regulatory advice. FDA regulation text quoted is public (21 CFR). ISO, IEC and AAMI standards are copyrighted; this kit paraphrases and cites clause numbers only, so buy the standards from ISO/ANSI/AAMI. Confirm current requirements for every market, and use qualified regulatory support for submissions and reportability decisions.

Summaries of Regulation (EU) 2017/745 are paraphrased navigation aids; read the official text on eur-lex.europa.eu. Harmonised standards are referenced by number only.

About the author

Built by Matt Norman, US Navy veteran and former SpaceX Falcon 9 quality inspector and QA supervisor. (Not affiliated with or endorsed by SpaceX.) Norman Quality Tools is Veteran-Owned & Operated. Contains no SpaceX, government, or customer proprietary information; all example data is made up.

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Technical Documentation Starter (Annex II/III structure)

EU MDR Technical File Starter Kit - Document 01 - Rev A (2026-10)

Structure follows Regulation (EU) 2017/745 Annexes II and III (EU legislation is freely available at eur-lex.europa.eu; this kit summarizes rather than reproduces it). Use one file per device or device group with the same Basic UDI-DI.

Device name / Basic UDI-DI		Risk class + classification rule	
Manufacturer / SRN		Authorized representative (if non-EU)	
Notified Body (if applicable)		PRRC (Art. 15)	

Section	Content	Reference	Doc # / rev	Status
1	Device description and specification, incl. variants and accessories	Annex II 1		
2	Information supplied by the manufacturer (labels, IFU)	Annex II 2		
3	Design and manufacturing information	Annex II 3		
4	General safety and performance requirements (GSPR) checklist	Annex II 4 / Annex I		
5	Benefit-risk analysis and risk management	Annex II 5		
6	Product verification and validation (pre-clinical, clinical evaluation)	Annex II 6		
7	Post-market surveillance plan, PMS report / PSUR	Annex III		
8	Declaration of conformity	Annex IV		
9	UDI, Basic UDI-DI, EUDAMED registration	Art. 27-29		
10	Classification rationale	Annex VIII		

Classification rationale

Rule(s) applied, duration, invasiveness, active?, reasoning

Declaration of conformity checklist

- Manufacturer and AR details; SRN
- Basic UDI-DI; product and trade name
- Statement of sole responsibility; risk class
- Regulation and harmonised standards / common specifications applied
- Notified Body name, number, certificate (if applicable)