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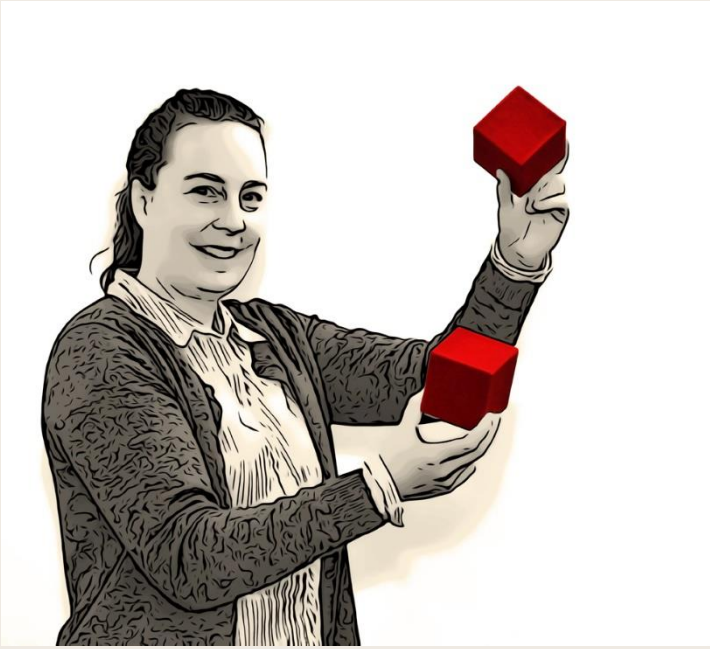
Technical Documentation

for medical devices under EU MDR - 2017/745

Nicole Gabathuler

Nicole Gabathuler – Senior Consultant



Bachelor of Business Administration, Manager Regulatory Affairs International TUV, CAS in Medical Technology. 10+ years of experience in global medical device registrations and quality management systems according ISO 13485, 21 CFR Part 820, and SOR/98-282. Worked for Disetronic AG (Roche Diabetes Care) and Institut Straumann AG. Joined confinis 2013 and is supporting different medical device start-ups and university spin-offs as well as multinational companies in regulatory affairs and quality management.

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MDR Key References

MDR Key References

- (Pre)-Articles 5: international guidance

As in the MDD the list of required documents was not always specific and less exhaustive the manufacturers often relied on recommendations like from GHTF-STED document. Now the MDR explicitly says that international guidance like the ones developed by GHTF / IMDRF should be taken into account when establishing for example the TD to promote the global convergence of regulations.

- Chapter II, Article 10, point 8, paragraph 2: Summary of TD

New the Notified Body can ask for a Summary of the TD like the GHTF STED. This was not the case in the MDD even though already now some NBs are asking for it.

MDR Key References

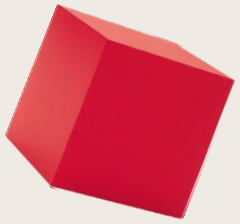
- Chapter II, Article 15, point 3b): Person responsible for regulatory Compliance is responsible to ensure that RA TD is existing and up to date

- Chapter V, Article 52, point 12: language requirement of TD

Always a discussion is the language requirement of the TD. The MDR states that the Member State where the NB has its place of business determines the language of the TD. If there is no such requirement the Notified Body decides on a language (any official Union language is possible).

MDR Key References

- Annex II: Content of Technical Documentation
- Annex III: Content of Technical Documentation on Post-Market Surveillance



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Key changes

Key changes

- Content of TD is defined more precisely (clearer)

- Newly added:
  - Post-market surveillance TD acc. Annex III
  - UDI
  - Rational why product is a MD
  - Not applicable GSPR requirements need to be explained (Annex II, point 4a)
  - Definition why product is a single-use device needs to be justified
  - Implant card acc. Article 18
  - GSPR (Annex I, point 23.4 s) ff.): user/patient information

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New and changed requirements

New and changed requirements

- Comparison between MDD and MDR not useful as MDD does not say a lot about TD.

MDD (Annex VII, Section 3)	MDR (Annex II)
General Description (incl. manufacturing method)	Section 1, Section 3
Risk Management (incl. Standard list)	Section 5
Sterility	Section 6
Connection to other devices	Section 6.2 g)
ERM	Section 4
Pre-Clinical Evaluation	Section 6
Clinical Evaluation	Section 6
Labels and IFU	Section 2

→ Therefore comparison with GHTF STED was chosen

New and changed requirements

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1. Device description and specification including variants and accessories

	MDR	GHTF STED
Section:	1.1 Device Description 1.2 Reference to previous and similar generations of the device	6.1 Device Description 6.2 Product Specification 6.3 Reference to similar and previous generations of the device
New: (not incl. in STED)	- intended users (could be taken from Clinical Evaluation) - UDI - rationale why product is a MD	
Changed:	- Patient selection criteria (covered in diff. Section of STED (e.g. (contra)-indication), not own chapter) - Classification - Previous and similar generations is new to TD	
Other Input to be considered:		

New and changed requirements

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2. Information to be supplied by the manufacturer (Labeling)

	MDR	GHTF STED
Section:	2. Information to be supplied	7. Labeling
New: (not incl. in STED)	- Website	
Changed:	- Content of label (material, UDI, MD) - Content of IFU (clinical benefit, link to summary about safety and performance)	
Other Input to be considered:	Annex I, Chapter III, Clause 23	GHTF Guideline «Labelling for Medical Devices» GHTF/SG1/N43:2005

New and changed requirements

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3. Design and Manufacturing Information

	MDR	GHTF STED
Section:	3 a) – c)	8.1 Device Design 8.2 Manufacturing Process 8.3 Design and Manufacturing Sites
New: (not incl. in STED)	- Development Plan and/or Design Stages (requested in STED, but mainly not provided)	
Changed:	n/a	
Other Input to be considered:		

New and changed requirements

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4. General Safety and Performance Requirements (ERM/EP Checklist)

	MDR	GHTF STED
Section:	4. GSPR	9. Essential Principles Checklist
New: (not incl. in STED)	n/a	
Changed:	- MDD ERM resp. STED EP to MDR GSPR	
Other Input to be considered:	Annex I	

New and changed requirements

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5. Benefit-Risk Analysis and Risk Management

	MDR	GHTF STED
Section:	5. Benefit / Risk Mgmt	10. Risk Analysis and Control Summary
New: (not incl. in STED)	n/a	
Changed:	- A summary as provided in the STED is not enough, see input to be considered below	
Other Input to be considered:	Annex I, Section 1, 3 and 8	

New and changed requirements

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6. Product Verification and Validation

	MDR	GHTF STED
Section:	6.1a) – c) Engineering, Simulated use, Animal tests, Software V&V, Biocompatibility, Shelf life, d) PMCF plan/report 6.2 specific cases	11.1 - 2, 5 - 8 General, Biocompatibility, Sterilization, Software V&V, Animal Study, Clinical Evaluation 11.3 - 4 Medicinal Substances, Biological Safety
New: (not incl. in STED)	- PMCF plan and report	
Changed:	n/a	
Other Input to be considered:	Art. 61, point 2), 7) and 12), Annex I (GSPR), Annex XIV, Part A, point 4 and Part B, Point 6 and 7	

New and changed requirements

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Annex III: TD on Post-market Surveillance

	MDR	GHTF STED
Section:	Annex III	n/a
New: (not incl. in STED)	1.1 PMS Plan 1.2 PSUR and PMS Report - Though STED is not used for post-market surveillance some information like market history, recalls and incident reports need to be included for registrations	
Changed:	n/a	
Other Input to be considered:	Articles 83 - 86	

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Actions required

Actions required

- Check if there is a STED according GHTF available
- If yes:
  - Establish missing parts (see previous sections of presentation)
  - Check if parts covered in STED according GHTF are detailed enough for MDR
  - Update TD Table of Content Template according MDR
  - Update the referenced Annexes (if any) in the STED according to the new Table of Content Template
- If no:
  - Update TD Table of Content Template according MDR Annex II
  - Check for missing parts according Table of Content and Annex I
  - Write a STED according Annex II and GHTF input