Your Regulatory Partner

Technical documentation for medical devices according to MDR – Webinar in cooperation with Swedish Medtech, 2020-06-05

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sis STANDARD DEVELOPER 2019

SEK SVENSK ELSTANDARD

EA AR European Association of Authorised Representatives

SWEDISH Medtech

QAdvis – Key competence areas

QMS In-the-cloud

Turn Key QMS
Digital Signatures
Efficient and Lean

System Development

Product Software Validation
Computer Systems Validation
Risk Management
Verification and Validation
Process Validation

European Authorised Representation

Providing European representation for non-EU MedTech companies
Active member of EAAR (European Association of Authorized Reps)

Training/Courses

CE-Marking, MDR, IVDR
ISO 13485 & QSR & MDSAP
IEC 62304 & IEC 82304-1
IEC 60601-1
IEC 62366-1
Risk Management
And more…

Agile, Lean and Six Sigma

Training and consulting in cooperation with US partner

QA&RA/Clinical Consulting

Interim Management, Expert Advise
Audits/Mock audit/Due Diligence
Warning Letters, Compliance Projects
PMA, 510k, CE-Marking, Tech Files
Global Regulatory Support
Vigilance, Recalls, PMS
Clinical Evaluation and Clinical Studies

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Presentation of the speaker - Maria Eklycke

(maria.eklycke@qadvis.com)

Work experience:

- Medical device testing
  - EN 60601-1
  - EN 61010-1
- Notified Body for medical devices
  - Product assessment
  - Review of technical documentation (active and non-active devices)
- Quality and regulator consultant

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Agenda

- Why technical documentation
- Contents of technical documentation Annex II and III
- Technical documentation, do and don´t (common mistakes)
- Recommendations
- Conclusion

Why technical documentation?

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General obligations of manufacturers

"Manufacturers of devices other than custom-made devices shall draw up and keep up to date technical documentation for those devices. The technical documentation shall be such as to allow the conformity of the device with the requirements of this Regulation to be assessed. The technical documentation shall include the elements set out in Annexes II and III."

(MDR Article 10)

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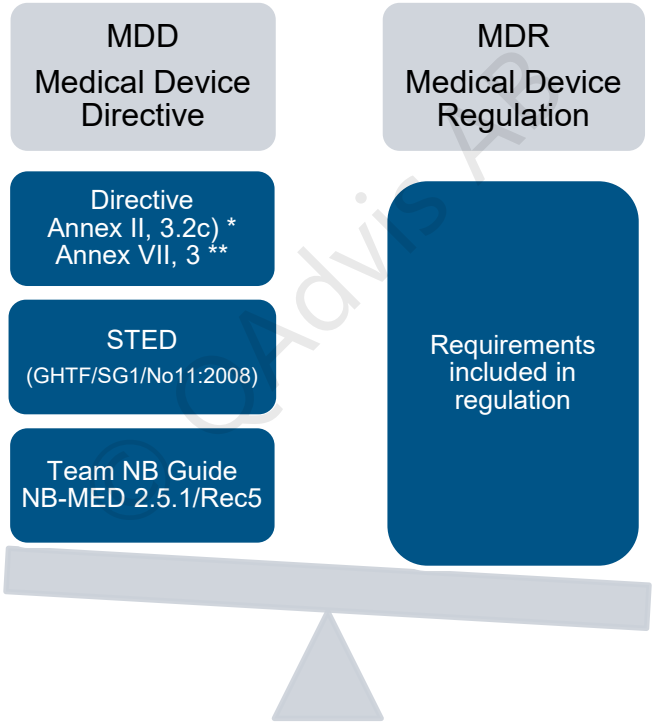
Requirements on technical documentation



* MDD Annex II: Full quality assurance system
** MDD Annex VII: EC Declaration of Conformity

Contents of technical documentation MDR

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Technical documentation

- Technical documentation (Annex II)
- Technical documentation on post-market surveillance (Annex III)
- General safety and performance requirements (Annex I)
- Clinical evaluation (Annex XIV)
- Declaration of conformity (Annex IV)

(MDR Annex I, II, III, IV, XIV)

Technical documentation – Annex II

1. Device description and specification, including variants and accessories
2. Information to be supplied by the manufacturer
3. Design and manufacturing information
4. General safety and performance requirements
5. Benefit-risk analysis and risk management
6. Product verification and validation

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Technical documentation on post-market surveillance – Annex III

1. Post market surveillance plan (Article 84)

2. Class IIa, IIb and III
Periodic safety update report (PSUR),
(Article 86)

- Conclusion of risk benefit
- Main findings of PMCF
- Volume of sales, size of population using the device

3. Class I
Post-market surveillance report, class I devices
(Article 85)

- Conclusion of PMS data

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Technical documentation, do and don’t (common mistakes)

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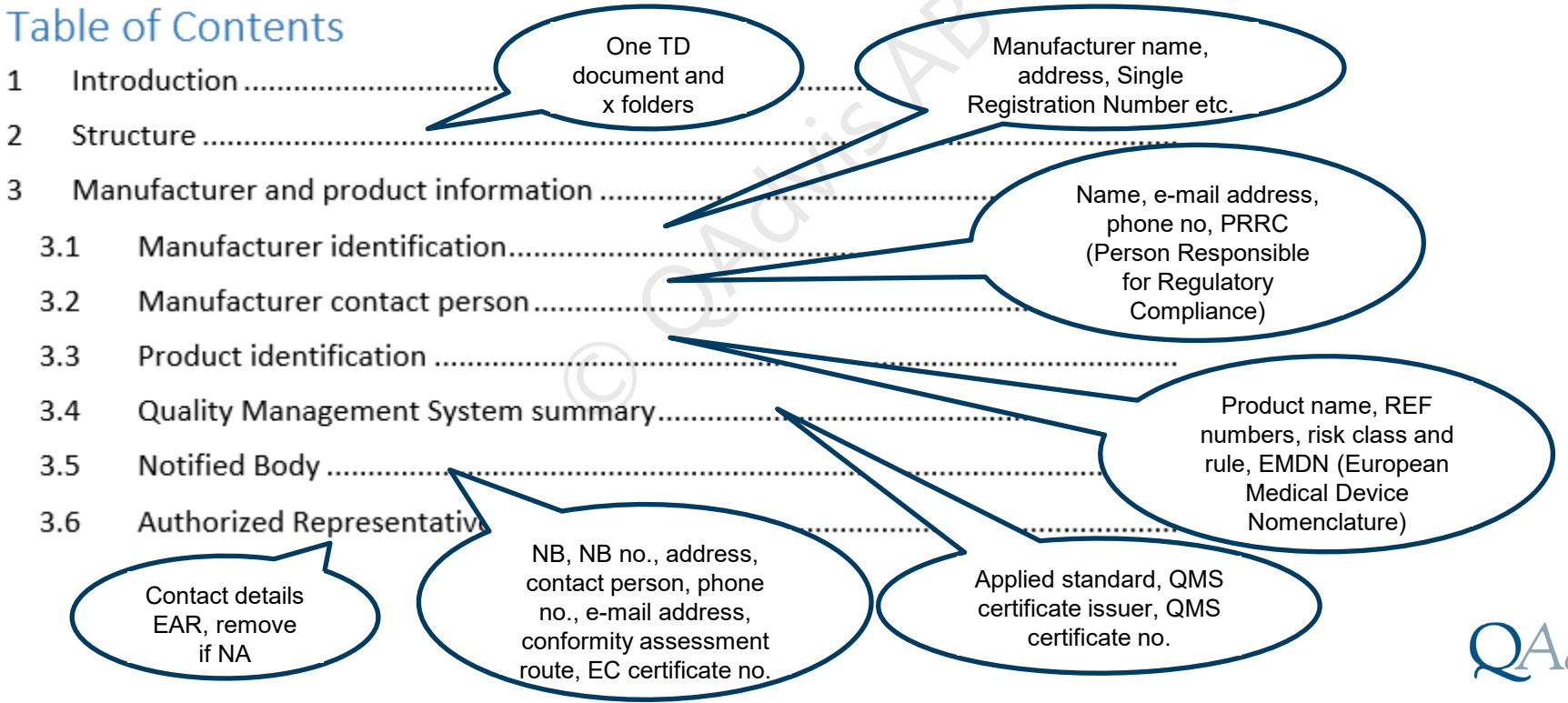
Technical documentation structure – Example



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Technical documentation structure – Example

Annex II

Annex III

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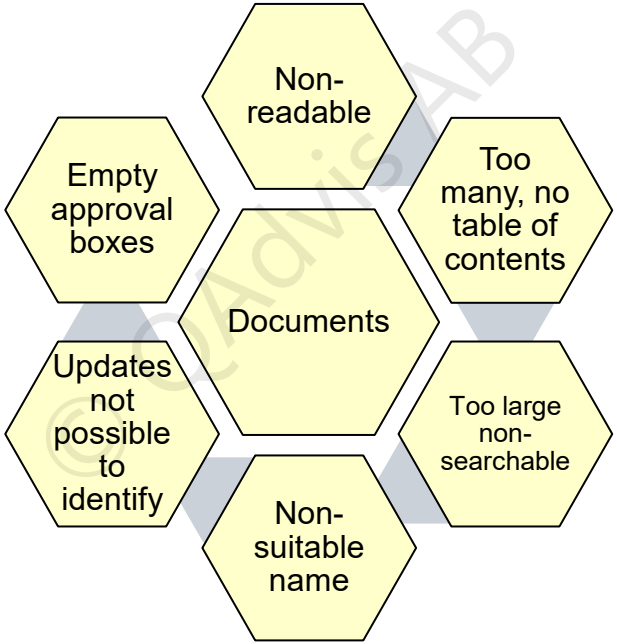
Administrative issues – Do

"The technical documentation and, if applicable, the summary thereof *to be drawn up by the manufacturer shall be presented in a clear, organised, readily searchable and unambiguous manner and shall include in particular the elements listed in this Annex."**

Notified Body specific requirements ? (file types etc.)	Document version handling (Doc. ID, Doc. version No.)	Doc. history/ change	Structure according to MDR Annex II and III	Appropriate document names

(*MDR Annex II)

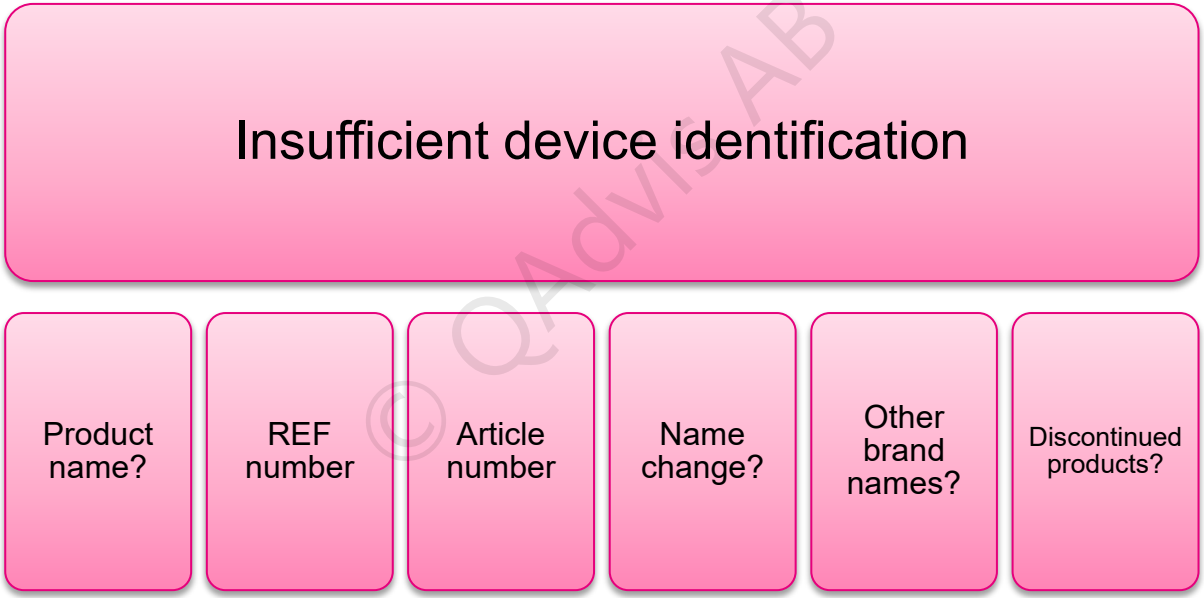
Administrative issues – Don’t



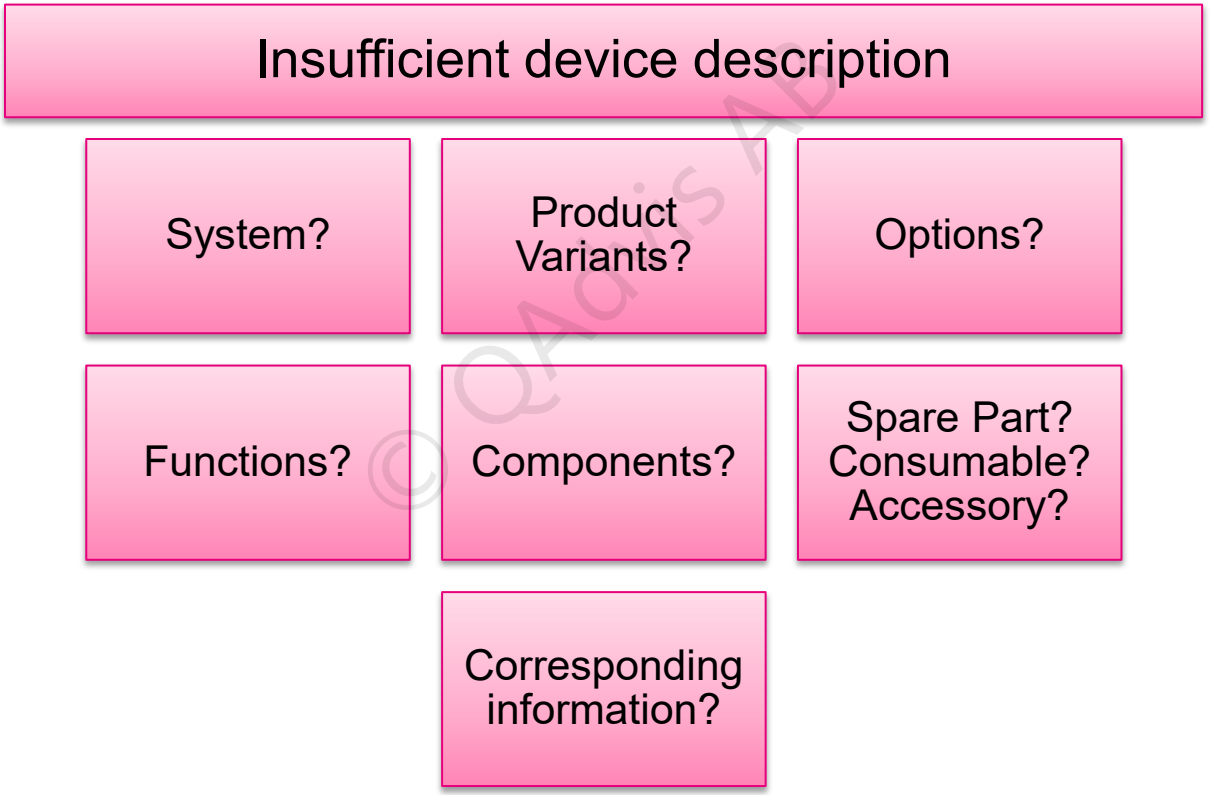
Device identification and description - Do

- Clear device identification
  - Product name
  - Trade name
  - Product code
  - Article number
  - REF number
  - UDI-DI
- Clear device description

Device identification – Don’t



Device description – Don’t



Device description– Don’t – Example

Document	Technical File	DoC	Product Specification
Product Description	System (No accessories)	Generator, Accessories and Probes	Generator and Probes (No accessories)
Product Identification	Generator	Generator REF A	Generator REF A
		Gas Regulator	
		Foot switch	
		Probes	
	Probe-0.5B	Probe-0.5B	
			PROBE-0.5C
			PROBE-0.5N
	PROBE-1B	PROBE-1B	PROBE-1B
	PROBE-1N	PROBE-1N	PROBE-1N
	PROBE-1BR		
	PROBE-1NR		
	PROBE-2B	PROBE-2B	PROBE-2B
			PROBE-2N
	PROBE-3B	PROBE-3B	PROBE-3B
	PROBE-3N	PROBE-3N	PROBE-3N
	PROBE-4B	PROBE-4B	PROBE-4B
	PROBE-4N	PROBE-4N	PROBE-4N
	PROBE-3BR	PROBE-3BR	PROBE-3BR
	PROBE-3NR	PROBE-3NR	PROBE-3NR
	PROBE-4BR	PROBE-4BR	PROBE-4BR
	PROBE-4NR	PROBE-4NR	PROBE-4NR

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General safety and performance requirements – Do

Traceability:
Requirements => Methods => evidence!

No.	General Safety and Performance Requirements, … MDR 2017/745	…	… ocument(s) … each method … reference to the location … the full technical documentation.
I	GENERAL REQUIREMENTS		
1	Devices shall achieve the performance intended by their manufacturer and shall be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose. They shall be safe and effective and shall not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety, taking into account the generally acknowledged state of the art.		
2	The requirement in this Annex to reduce risks as far as possible means the reduction of risks as far as possible without adversely affecting the benefit-risk ratio.		
3	Manufacturers shall establish, implement, document and maintain a risk management system.		

- Complete references (version, year etc)
- State of the art
- Priority 1:
  Refer to European guidelines or standards (EN versions)
  Priority 2:
  Refer to international guidelines or standards
- Rationale if not applicable

- Refer to precise document identity
- It shall be clear which method that corresponds to which documented evidence

(Annex I and II, 4)

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General safety and performance requirements – Do - Example

No.	General Safety and Performance Requirements, Annex I – MDR 2017/745	A/NA	Reference to the methods used to demonstrate conformity, harmonized standards, CS or other solutions applied. (Rationale if NA)	The precise identity of the controlled document(s) offering evidence of conformity with each method used, including a cross-reference to the location within the full technical documentation.
I	GENERAL REQUIREMENTS			
1	Devices shall achieve the performance intended by their manufacturer and shall be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose. They shall be safe and effective and shall not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety, taking into account the generally acknowledged state of the art.	A	1. EN 60601-1:2006 EN 60601-1:2006/A1:2013 2. EN 60601-1-2:2015 3. SS-EN 62366-1:2016 4. EN ISO 14971:2012 5. MEDDEV 2.7/1 Rev 4 6. Test specifications; Hardware Doc ID xx, Version xx Software Doc ID xx, Version xx	1. Electrical safety test report, Doc ID xx, Version xx 2. EMC test report, Doc ID xx, Version xx 3. Usability Engineering File, documents: Doc ID xx, Version xx Doc ID yy, Version yy Doc ID zz, Version zz 4. Risk Management File; RM Procedure, Doc ID xx, Version xx RM Plan, Doc ID xx, Version xx RM Report, Doc ID xx, Version xx Risk Analysis 1, Doc ID xx, Version xx 5. Clinical Evaluation Report, Doc ID xx, Version xx 6. Verification Summary Report, Doc ID xx, Version xx

Add location in TD

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General safety and performance requirements – Don't – Example

Traceability:
Requirements => Methods => evidence?

No.	General Safety and Performance Requirements, Annex I MDR 2017/745		solutions applied. (Rationale if NA)	identity of the controlled document(s) offering evidence of conformity with each method used, including a cross-reference to the location within the full technical documentation.
I	GENERAL REQUIREMENTS			
1	Devices shall achieve the performance intended by their manufacturer and shall be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose. They shall be safe and effective and shall not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety, taking into account the generally acknowledged state of the art.			
2	The requirement in this Annex to reduce risks as far as possible means the reduction of risks as far as possible without adversely affecting the benefit-risk ratio.			
3	Manufacturers shall establish, implement, document and maintain a risk management system.			

Inappropriate references:
- MDR
- Non-European legislation

Non-complete references
- Reference to some applied standards only

Inappropriate references:
- "Design History File"
- "Technical File"
- "Project number X"
- "Risk Management Documents"
- "Safety test reports"
- "Biocompatibility testing"
- "Design documents"
- Etc.

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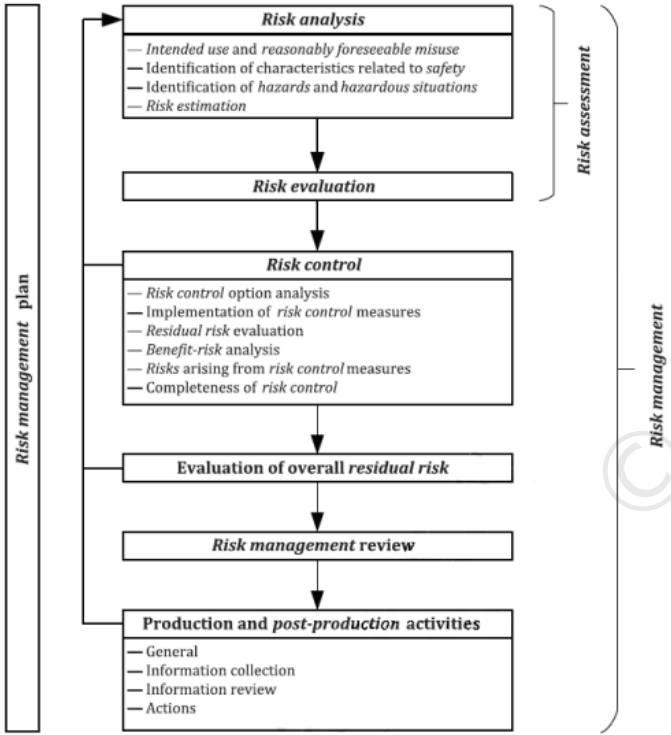
Risk management – Do



- Follow EN ISO 14971
  - Risk analysis
  - Risk evaluation
  - Risk control
  - Evaluation of overall residual risk
  - Risk management review
  - Production and post-production information

(SS-EN ISO 14971:2020)

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Risk management – Don’t – Example

Definition of severity

S Effects		
Ranking	*Definition*	*Use and Design Clinical Effects; Process End Effects*
9..10	Catastrophic	Serious injury (irreversible) or death of the patient or user; very severe negative effect on the environment.
7..8	Critical	Serious injury (reversible) to the patient or user; severe negative effect on the environment. Note: Any labelling issues that could lead to a field action must be ranked at a minimum of 4.
4..6	Moderate	Moderate injury to the patient or user; moderate negative effect on the environment. Decline of product performance or user confidence in the product/company (e.g. customer is very annoyed or dissatisfied).
2..3	Minor	Minor injury to the patient or user; minor negative effect on the environment. Slight decline of product performance or user confidence in the product/company (e.g. customer slightly annoyed or inconvenienced).
1	Negligible/ Cosmetic	No/virtually no injury to the patient or user; no/virtually no negative effect on the environment. No impact on product performance or user confidence in the product/company; user may or may not even notice the failure.

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Risk management – Don’t – Example

Severity Definitions	
• Negligible severity =	No or minor (clinically acceptable) injury, discomfort, and/or nuisance to patient, user, or environment that resolves without the need for medical/clinical intervention.
• Marginal severity =	Non-serious, non-life-threatening injury or discomfort that requires medical/clinical intervention to prevent permanent impairment of body structure or function.
• Critical severity =	Potential of death, serious injury (permanent impairment of body structure or function).
• Catastrophic severity =	Potential of multiple deaths or serious injuries from exposure to a single device or device-use.

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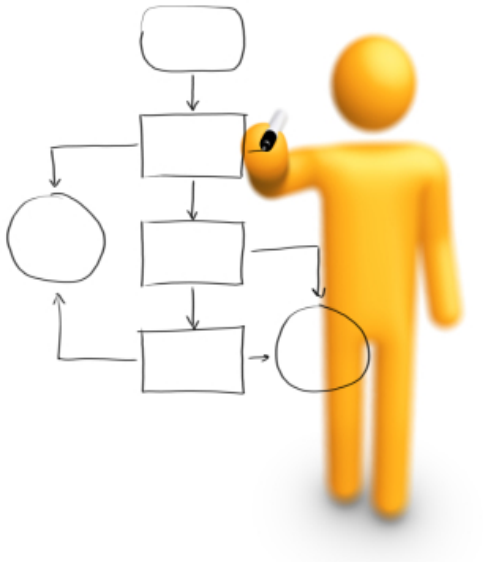
Clinical evaluation – Do



- Plan, continuously conduct, and document
- Clinical evaluation plan
- Identify clinical data
- Appraise
- Generate
- Analyse – reach conclusion: Safety, clinical performance including its clinical benefit

(MDR Annex XIV)

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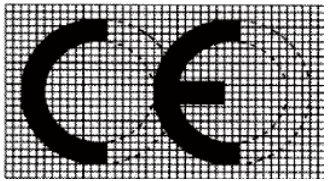
Clinical evaluation – Do

- Follow MEDDEV 2.7/1 Rev 4
- Level of clinical evidence needed vs GSPR:s
  - Specified and justified
  - Appropriate for the device and its intended purpose (all claims)
  - Clinical safety and performance
  - Sufficient specification of equivalence, if applicable
- Acceptability of the benefit-risk ratio for all indications

(Annex XIV, MEDDEV 2.7/1 Rev 4)

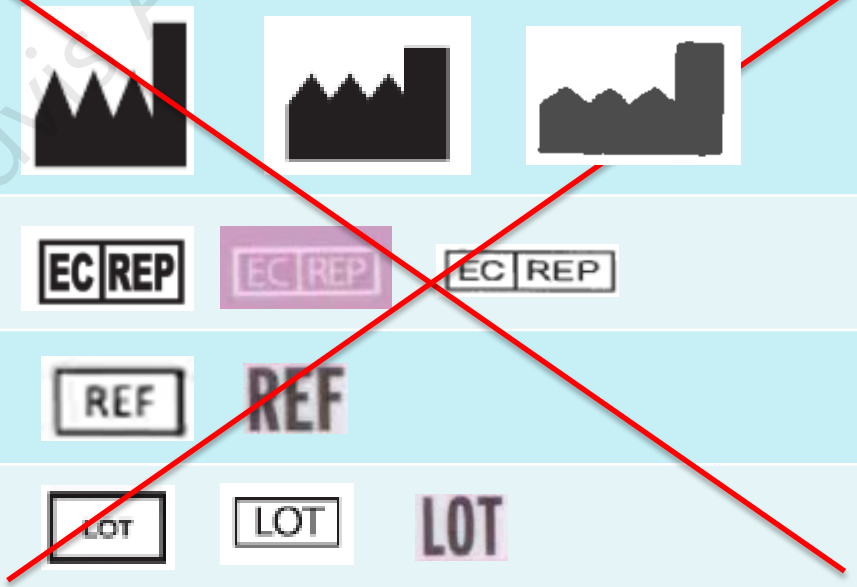
Symbols – Do



- Use correct symbols from harmonized standards or Common Specifications
- MDR Annex V

(MDR Annex I, ER 23.1 h), MDR Annex V)

Symbols – Don’t – Examples

Title of symbol	Correct	Incorrect
Manufacturer		
Authorized representative		
Catalogue number		
Batch code		

(EN ISO 15223-1:2016)

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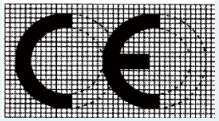
Symbols – Don’t – Examples

Title of symbol	Correct	Incorrect
Temperature limit		 
Consult instructions for use		 
Refer to instruction manual		
CE marking		  

(EN ISO 15223-1:2016, IEC 60601-1 d 3.1, MDR Annex V)

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Recommendations

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Administrative issues

"The technical documentation and, if applicable, the summary thereof *to be drawn up by the manufacturer shall be presented in a clear, organised, readily searchable and unambiguous manner and shall include in particular the elements listed in this Annex."*

(MDR Annex II)

Make sure the following is clear and sufficient

Product identification

- Unique identification
- Rationales if necessary (brand names, discontinued products etc.)

Device description

- Rationale for the qualification of the product as a device
- Classification rationale
- Complete requirement specification
- System, accessories, consumables etc.?

Traceability GSPR

- Reference to method of compliance
- Reference to evidence of compliance
- Rationales for non-applicable requirements

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Make sure the following is clear and sufficient

Risk management	• EN ISO 14971 • Sufficient risk management team competences (Risk Management, technological, clinical, biocompatibility etc.)
Evaluation of clinical data	• MEDDEV 2.7/1 Rev 4 • MDR Annex XIV and article 61 • Safety and performance • Meet all claims?
Symbols	• EN ISO 15223-1 • Use appropriate symbols, do not cut and paste from internet

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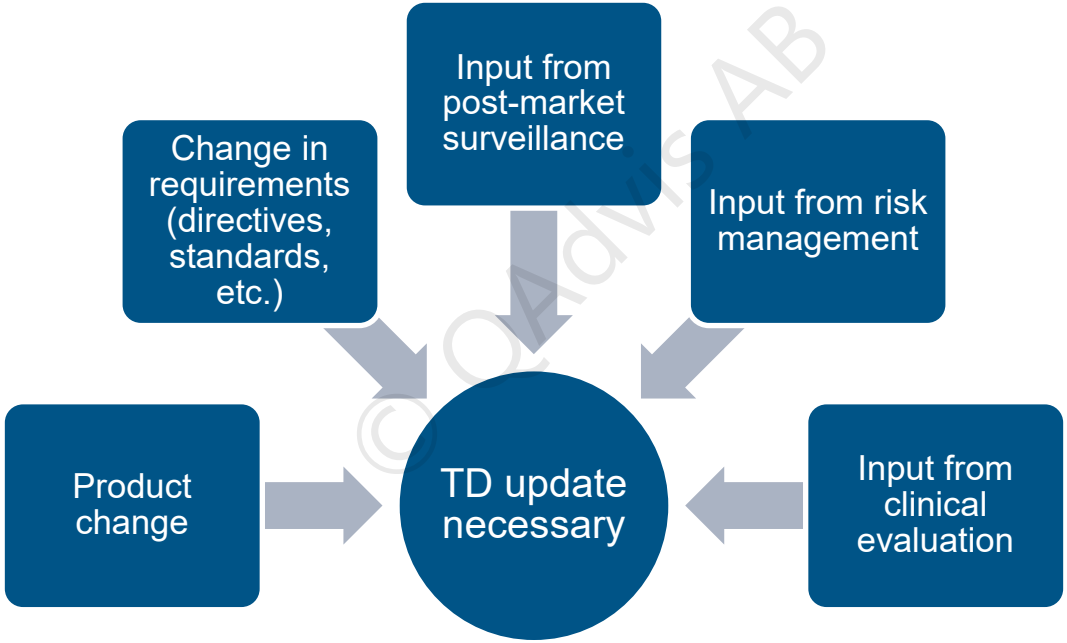
Technical documentation updates



Conclusion

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Conclusion

Documentation

- Well structured
- Clear identification of documents
- Relevant information
- Complete documentation

Internal review before submittal

- Complete traceability
- Rationales if appropriate
- Does it make sense?

Result

- Facilitate reviews
- Keep down review time and costs
- Shorten time to market!

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QAdvis services

- "Pre-flight" check of technical documentation
- Courses
  - CE-marking
  - Technical documentation
  - IVDR / MDR
  - Risk management
  - ISO 13485:2016
- Product specific workshop
- GAP analysis and implementation plan IVDR/MDR
- Quality Management System
- Auditing
- Risk management
- Clinical evaluation

www.qadvis.com/courses-and-seminars/

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TEKNISK DOKUMENTATION

Intresserad av att veta mer?
Vi håller kurs i höst på nedan datum!

- **16 september**
- **26 november**

Thank you for your attention!
Questions & answers

(Other questions: maria.eklycke@qadvis.com)

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Evaluation