Technical Files for Medical Devices – Common Mistakes

QAdvis – Seminar, Lund 2016-11-23 and Kista 2016-11-24

QAdvis Key Competence Areas

QMS In-the Cloud

Turn Key QMS
Digital Signatures
Efficient and Lean
Validated and Compliant

System Development

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

QA&RA/Clinical Consulting

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

Training/Courses

CE-Marking
ISO 13485 & QSR
IEC 62304 & IEC 82304-1
IEC 60601-1
IEC 62366-1
SW Life Cycle
SW Risk Management
Risk Management
And more…

Lean and Six Sigma

Training and consulting in cooperation with US partner.

European Authorised Representation

Providing European representation for non-EU MedTech companies

Active member of EAAR (European Association of Authorized Representatives)

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QAdvis Team

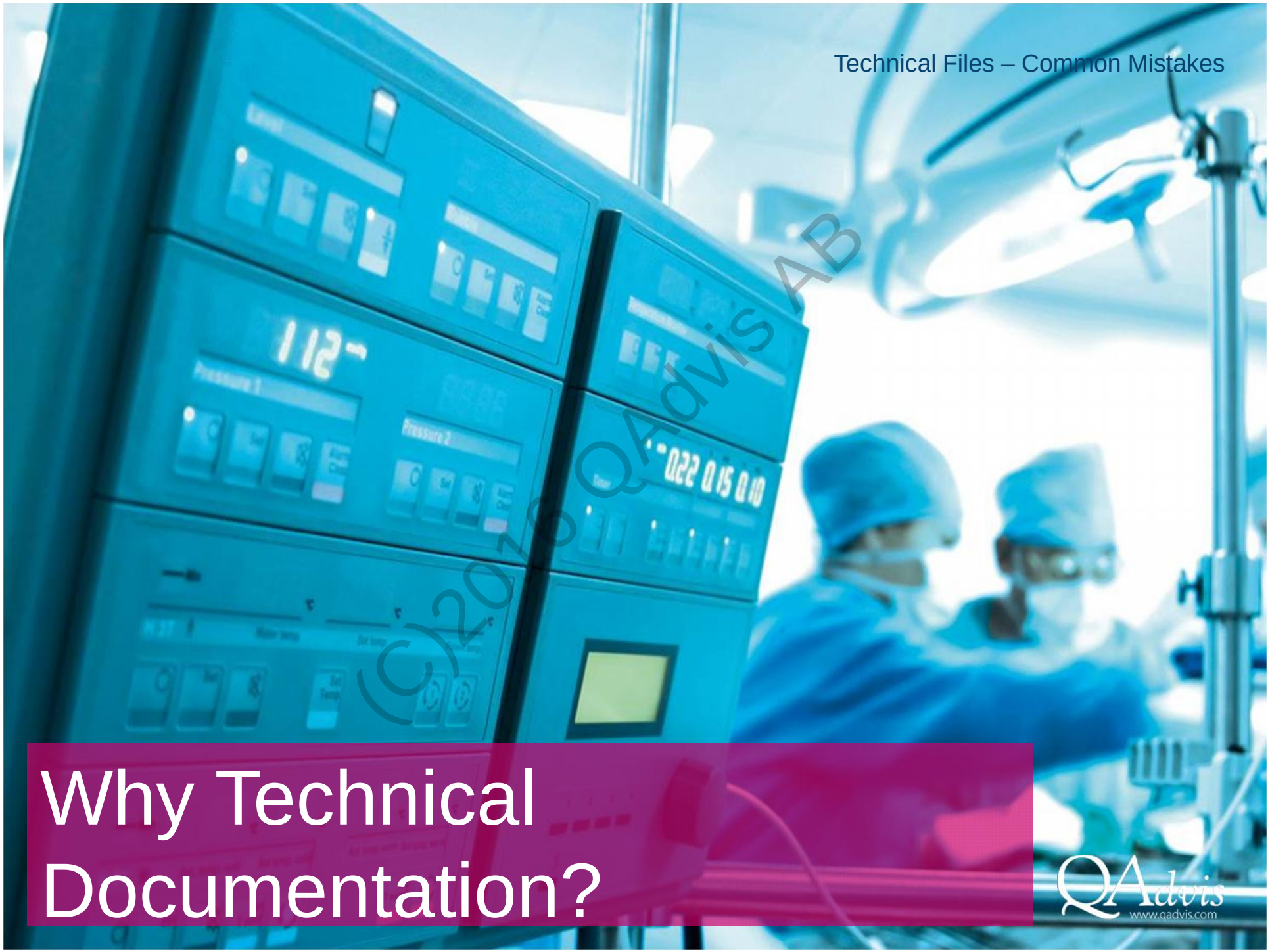
Presentation of the Speaker Maria Eklycke

Work experience:

- Medical Device testing
- Notified Body for Medical Devices
  - Product assessment
  - Review of Technical Files
  - Notified Body approval for a wide range of products (active and non-active devices)

Agenda

- Why Technical Documentation
- Contents of the Technical File
- Common Mistakes
- Conclusion



Why Technical Documentation?

Why Technical Documentation?

- Proof that the device conforms with the requirements in the Directive
- Available for inspection by:
  - National Competent Authority
  - Notified Body
- Live document, shall reflect changes in:
  - External Requirements
  - Product Changes
  - Input from Post Market Surveillance (PMS)

Technical Documentation

- Technical File (MDD Class I, IIa, IIb)
- Design Dossier (MDD Class III)

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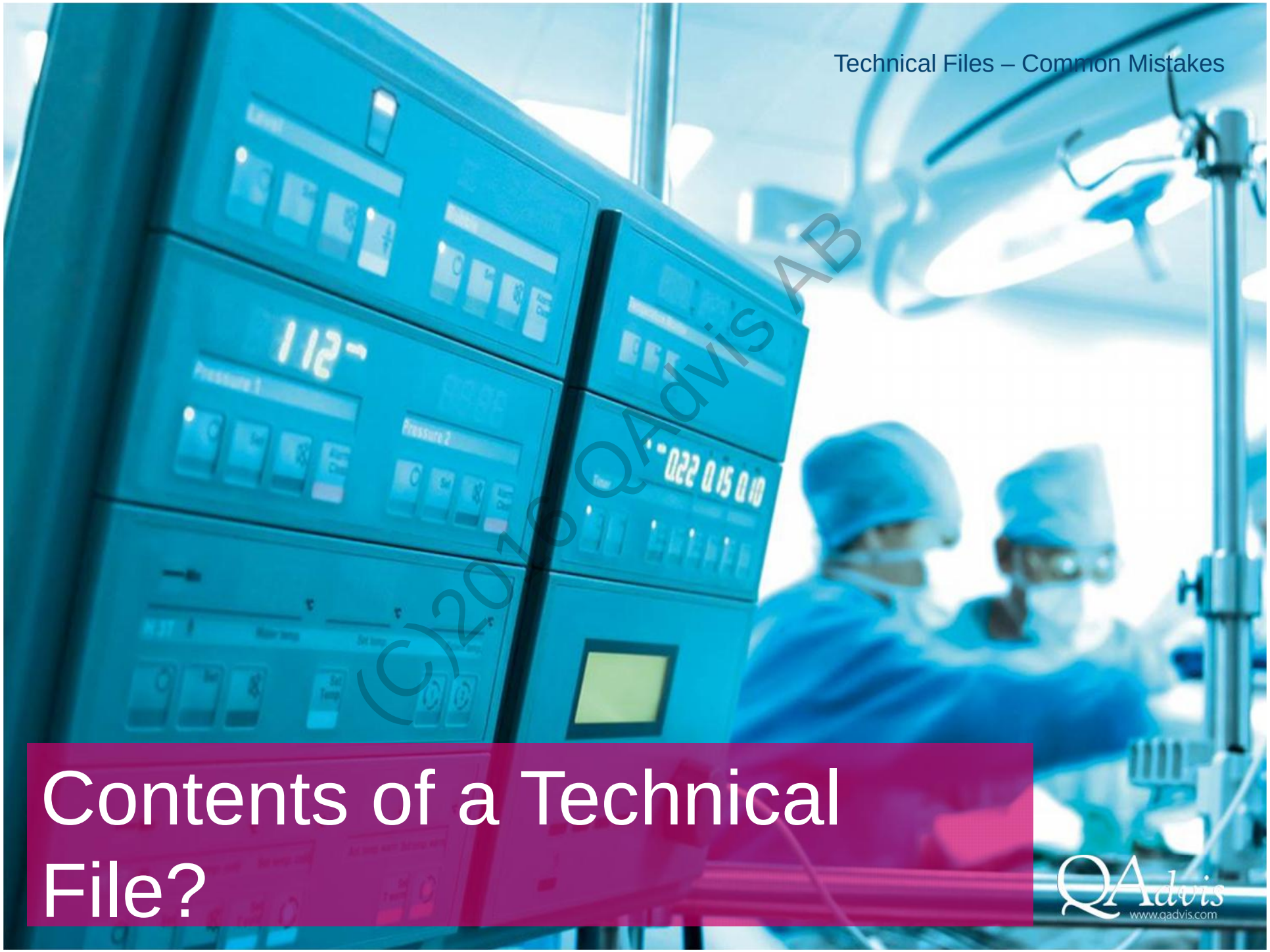
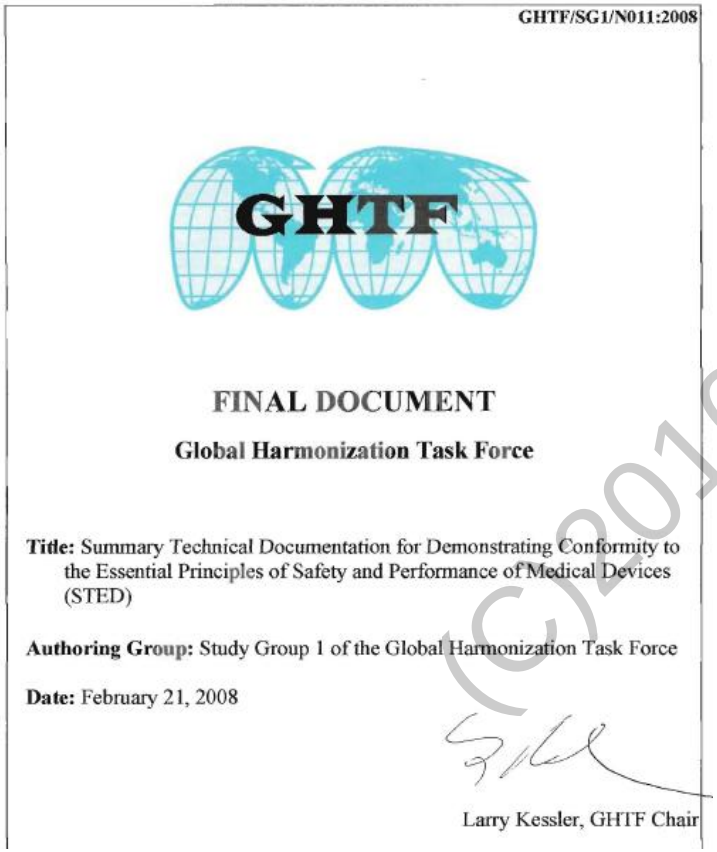


Contents of a Technical File?

Contents of the Technical File



GHTF/SG1/N011:2008

GHTF

FINAL DOCUMENT

Global Harmonization Task Force

Title: Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED)

Authoring Group: Study Group 1 of the Global Harmonization Task Force

Date: February 21, 2008

Larry Kessler, GHTF Chair

- STED
  (Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices)
- Team NB Guide NB-MED 2.5.1/Rec5 Technical Documentation
- Other European Guidelines

STED

- Device Description
- Product Specification
- Labelling
- Design and Manufacturing
- Essential Requirements
- Risk Analysis
- Verification and Validation
- Evaluation of Clinical Data
- Declaration of Conformity

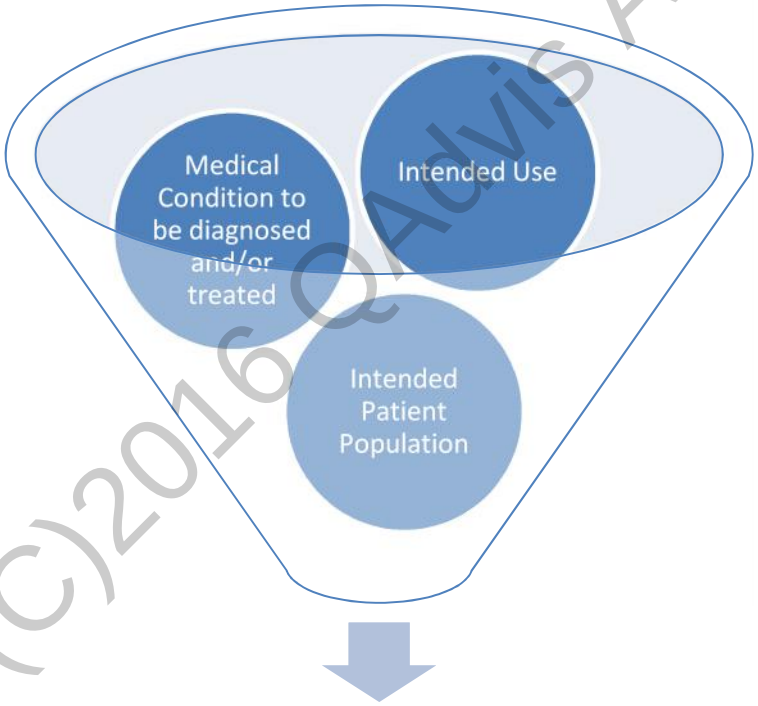
MDR and IVDR

(Annex II Technical Documentation)

- Device Description and Specification
- Information Supplied by the Manufacturer
- Design and Manufacturing
- General Safety and Performance Requirements
- Risk/Benefit Analysis and Risk Management
- Verification and Validation
- PMS
- (Declaration of Conformity, Annex III)

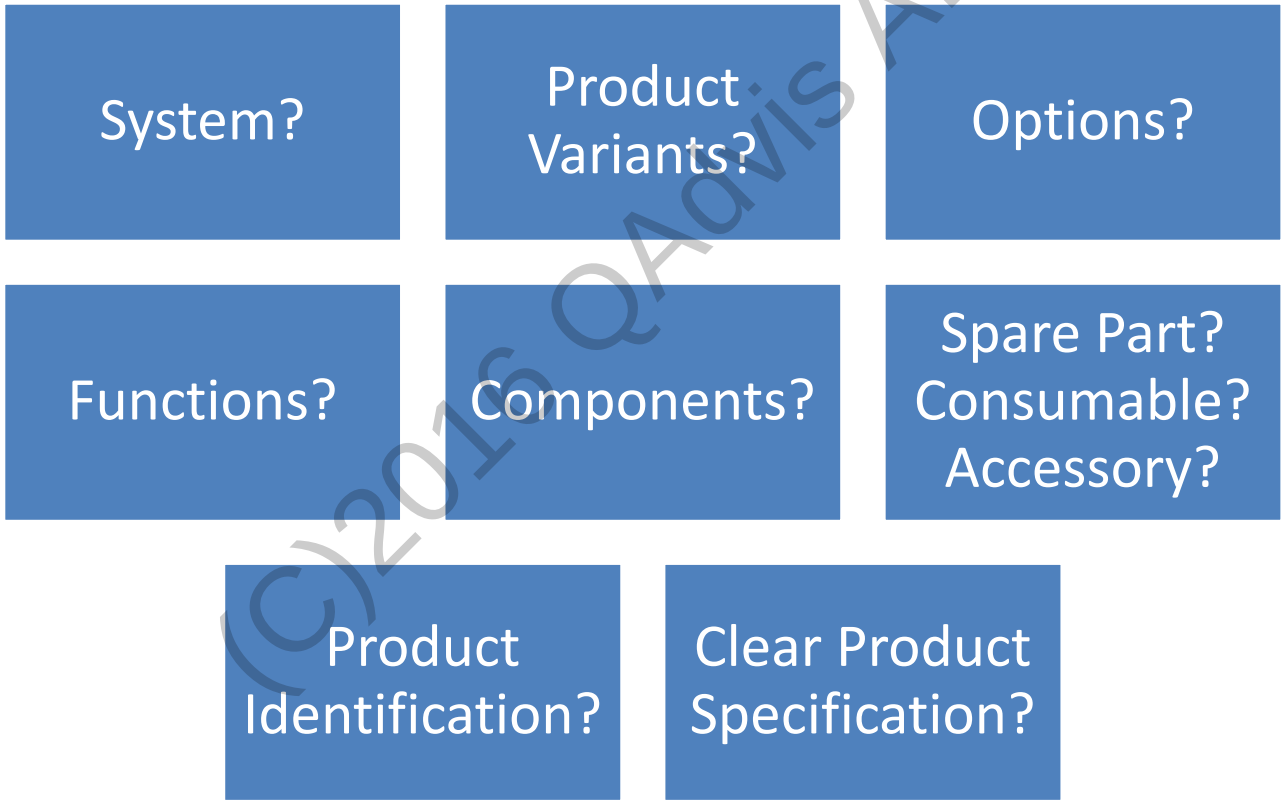
Common Mistakes

Insufficient Description of the Device



Medical Device?

Insufficient Description of the Device



Insufficient Description of the Device 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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Insufficient Traceability

No.	ESSENTIAL REQUIREMENTS – MDD 93/42/EEC	A/NA	Reference to the methods used to demonstrate conformity. (Rationale if NA)	The precise identity of the document(s) that offers evidence of conformity with each method used
I	GENERAL REQUIREMENTS			
1.	**Documentation Concerning Safe Use** The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of the patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their intended 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. This shall include: - reducing, as far as possible, the risk of use error due to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and - consideration of the technical knowledge, experience, education and training and where applicable the medical and physical conditions of intended users (design for lay, professional, disabled or other users).			
2.	**Documentation on Interpretation and Construction** The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking			

Insufficient Traceability Example

I.	GENERAL REQUIREMENTS				
1.	The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will 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 intended 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. This shall include: - reducing, as far as possible, the risk of use error due to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and - consideration of the technical knowledge, experience, education and training and where applicable the medical and physical conditions of intended users (design for lay, professional, disabled or other users).	Yes	ISO 13485:2003 and EN ISO 13485:2012 ISO 14971	Risk Management Tech File Section 6 Risk File 66 and 83 Quality Plan QP x and QP-y Device Master Record Index (DMRI) S30111 Process Qualification	The quality system meets the requirements of ISO 13485 and the Canadian Medical Devices Regulation. Hazard Analyses and Failure Modes and Effects Analysis (FMEA) were conducted in accordance with ISO 14971 to assess risk as part of design requirements. Process Failure Modes and Effects Analysis (PMEA) was conducted to assess risk during the manufacturing process. The Quality Plans summarize all required tests and inspections required to build the devices as designed.

Device: High Frequency Surgical Equipment

Insufficient Traceability Example

ISO 13485:2003 and EN ISO 13485:2012 ISO 14971	Risk Management Tech File Section 6 Risk File 66 and 83 Quality Plan QP x and QP-y Device Master Record Index (DMRI) S30111 Process Qualification

Device: High Frequency Surgical Equipment

Insufficient Traceability - Example

- Methods of compliance
  - EN ISO 14971:2012
  - EN 60601-1:2006
  - EN 60601-1-2:2015
  - EN 60601-2-2:2009
  - EN 62366:2008
  - EN 62304:2006
- Evidence of conformity
  - Unique references
  - For all methods
  - For all product variants

Insufficient Traceability - Example

Safety Compliance Tests	Product A	Product B	Product C	Product D	Product E	Product F	Product G	Product H
General Safety Testing	TR100Y10	TR100Y10	TR100Y10	TR100Y10	TR100Y10	TR100Y10	TR100Y10	TR100Y10
Material Biocompatibility	TR10010	TR10010	TR10010	TR10010	TR10010	TR10010	TR10010	TR10010
Material Flammability	TR10015	TR10015	TR10015	TR10015	TR10015	TR10015	TR10015	TR10015
Surface Temperature Test	TR0109	TR0121	TR0107	TR100X02	TR0107	TR100X02	TR100X02	TR100X02
Component Temperature Test	TR0108	TR0120	TR0120	TR0120	TR100Z3003	TR100Z3003	TR100X03	TR100X03
Risk Analysis	RA7P500	RA7P500	RA7P500	RA7P500	RA7P500	RA7P500	RA7P500	RA7P500
Electrical Safety								
FMEA	RA7P500	RA7P500	RA7P500	RA7P500	RA7P500	RA7P500	RA7P500	RA7P500
Hazard Analysis	RA7P500	RA7P500	RA7P500	RA7P500	RA7P500	RA7P500	RA7P500	RA7P500
Blocking Network Analysis	TR10001	TR10001	TR10001	TR10001	TR10001	TR10001	TR10001	TR10001
Dielectric Withstand Leakage Current	TR3000	TR3000	TR3000	TR3000	TR3000	TR3000	TR3000	TR3000
Mechanical Safety								
FMEA	RA7P500	RA7P500	RA7P500	RA7P500	RA7P500	RA7P500	RA7P500	RA7P500
Enclosure Mechanical Strength	TR10004	TR10004	TR10004	TR10004	TR10004	TR10004	TR10004	TR10004
Mechanical Safety Analysis	RA7P500	RA7P500	RA7P500	RA7P500	RA7P500	RA7P500	RA7P500	RA7P500
Hazard Analysis	RA7P500	RA7P500	RA7P500	RA7P500	RA7P500	RA7P500	RA7P500	RA7P500
Product Impact and Drop Tests	TR4000	TR4000	TR4000	TR4000	TR4000	TR4000	TR4000	TR4000
Labelling								
Identification and Markings	TR100X20	TR100X20	TR100X20	TR100X20	TR100X20	TR100X20	TR100X20	TR100Y10
Legibility and Durability of Markings	TR9000	TR9000	TR9000	TR9000	TR9000	TR9000	TR9000	TR9000
Use of Harmonized Symbols	TX10001	TX10001	TX10001	TX10001	TX10001	TX10001	TX10001	TX10001
Instructions for Use Review	TR10010	TR10010	TR10010	TR10010	TR10010	TR10010	TR10010	TR100X09
Reliability Tests								
Durability Tests – General	TR5000	TR5000	TR5000	TR5000	TR5000	TR5000	TR5000	TR5000
Durability Tests – Liquid Ingress	TR7000	TR7000	TR7000	TR7000	TR7000	TR7000	TR7000	TR7000
Durability Tests – Cleanability	TR9000	TR9000	TR9000	TR9000	TR9000	TR9000	TR9000	TR9000

Insufficient Traceability - Example

- Traceability matrix does not correspond to Essential Requirement Checklist (ERC)
- References to evidence of compliance in ERC and traceability matrix do not include all product variants
- Many Test Reports include insufficient product identification
- Not possible to evaluate if all applicable ER have been fulfilled for all product variants => Major NC!

Insufficient Risk Management

- Risks in both normal use and failure condition are not included
- All risks not identified
  - Complete team?
  - Warnings from IFU included?
- Benefit > Risk?
  - Non-suitable definitions?
- Incorrect calculation?

Insufficient Risk Management - Examples

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.

Index	1	2	3	4	5
Frequency of Occurrence	Remote	Occasional	Probable	Frequent	Always
Severity	Negligible Harm	Minor Injury	Major Injury	Critical Injury	Possible Death
Chance of Detection	Obvious	More Noticeable	Less Noticeable	Obscure	Undetectable

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Insufficient Risk Management - Examples

RPN	Classification	Required Action
1 - 10	Minor Risk	Apply risk controls in priority order until further risk reduction is not possible; perform risk-benefit analysis for each risk and the cumulative risk
10 - 20	Moderate Risk	
20+	Major Risk	

	Severity				
Probabilit	1	2	3	4	5
1	ACC	ACC	ACC	ACC*	ACC*
2	ACC	ACC	ACC*	ACC*	N ACC
3	ACC	ACC*	ACC*	N ACC	N ACC
4	ACC*	ACC*	N ACC	N ACC	N ACC
5	ACC*	N ACC	N ACC	N ACC	N ACC

Insufficient Evaluation of Clinical Data

- Clinical Safety and Performance?
- Evidence of fulfillment of its intended use?
- Meet all claims?
- ER fulfilled?
- Unclear description of equivalence?
- Include positive and negative data?
- Appropriate author?

Conclusion

Conclusion

- Well structured
- Clear identification of documents
- Relevant information
- Complete documentation
- Complete traceability
- Does it make sense?

- Facilitate internal and external reviews
- Keep down review time and costs
- Shortens time to market!

Thank you!
Questions & Answers

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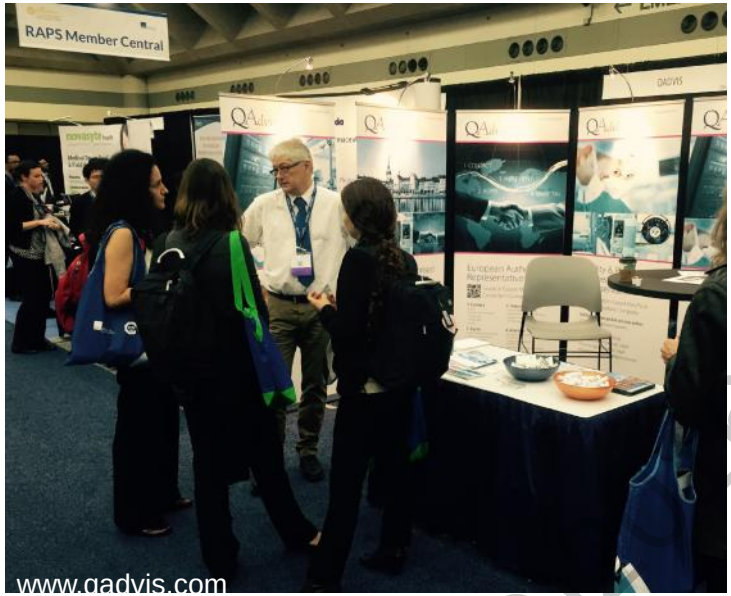
QAdvis can support you as needed



- CE marking process
- Compilation of Technical Files
- Review of Technical Files
- Classification review
- Risk Management

Contact:
maria.eklycke@qadvis.com
nils-ake.lindberg@qadvis.com
robert.ginsberg@qadvis.com

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References

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