Your Regulatory Partner

Breakfast Seminar
What's new in the ISO 14971:2019 standard?

Cristina.Barkman@QAdvis.com,
Maria.Rickardsson@QAdvis.com

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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 Cristina Barkman

- >20 years experience from development & manufacture of medical devices, quality assurance and regulatory affairs
- Expertise from risk management for medical devices
- Member of the international standardization committees ISO/IEC TC210 JWG1 and CEN/CLC/JTC 3

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Presentation of the speaker Maria Rickardsson

- >20 years experience in regulatory frameworks, quality assurance and risk management in medical device, software and telecom
- Extensive experience from ISO 13485, ISO 14971 and IEC 62304.

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What's in this seminar?

- History & Timeline
- Main changes in ISO 14971
- Main changes in ISO/TR 24971
- MDR/IVDR requirements on risk management

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History 1997 - 2019

- EN 1441:1997
- ISO 14971-1:1998
- ISO 14971:2000
- AM1:2003
- ISO 14971:2007
- EN ISO 14971:2012
- ISO 14971:2019

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European legislation

- **Directives 1993:**
  AIMDD, MDD, IVDMDD
  ER – Essential Requirements

- **Regulations 2017:**
  MDR, IVDR
  GSPR – General safety and Performance Requirements

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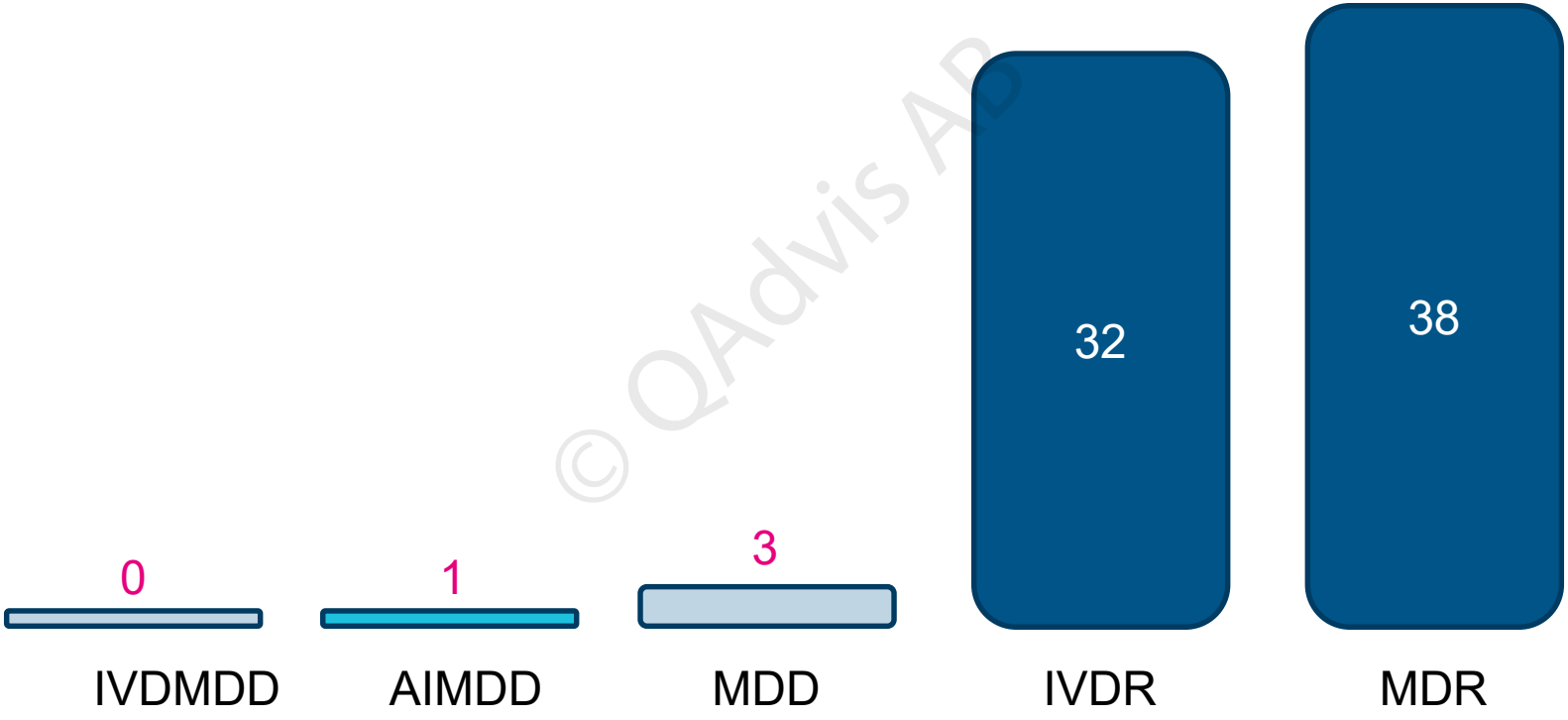
“Risk Management” in European Legislation

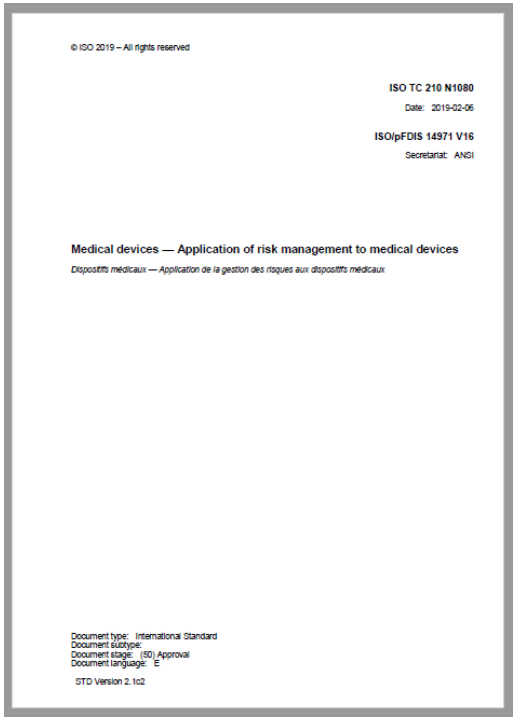


Scope of latest revision

- Adress comments from nationel committes
- Move most informative annexes to ISO/TR 24971
- Risk management process unchanged

Timeline

Main changes in ISO 14971:2019



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ISO TC 210 N1080

Date: 2019-02-06

ISO/pFDIS 14971 V16

Secretariat: ANSI

Medical devices — Application of risk management to medical devices

Dispositifs médicaux — Application de la gestion des risques aux dispositifs médicaux

Document type: International Standard
Document subtype:
Document stage: (50) Approval
Document language: E

STD Version 2.1c2

- Clauses restructured and revised
- Most annexes moved to ISO/TR 24971
- Process applicable for all types of medical device risks
- Defined terms updated
- Normative clause added

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Key changes: Benefit-Risk

- Definition of benefit added
- Aligned terminology
- Benefits expected from use

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Key changes: Overall residual risk

- Method to be defined in the plan.
- Criteria for its acceptability defined in the plan.
- Criteria can be different from the criteria for acceptability of individual risks.
- Disclosure of residual risk

Key changes: Risk management review

- Clarified that the review concerns the execution of the risk management plan.
- The results documented as the risk management report
- Plan for subsequent reviews and updates of RMR

Key changes: Production and post-production activities

- More details on information to be collected and reviewed.
- More details on actions to take when the information is determined to be relevant to safety.

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Key changes: Annexes

ISO 14971:2007	ISO 14971:2019
Annex A Rationale for requirements	**Annex A** Rationale for requirements
Annex B Overview of the risk management process for medical devices	**Annex B** Overview of the risk management process for medical devices
Annex C Questions that can be used…	Moved to ISO/TR 24971
Annex D Risk concepts applied to medical …	
Annex E Examples of hazards, …	**Annex C** Fundamental risk concepts
Annex F Risk management plan	Moved to ISO/TR 24971
Annex G Information on risk mgm techniques	
Annex H Guidance on risk mgm for in-vitro …	
Annex I Guidance on risk analysis process…	
Annex J Information for safety and about …	

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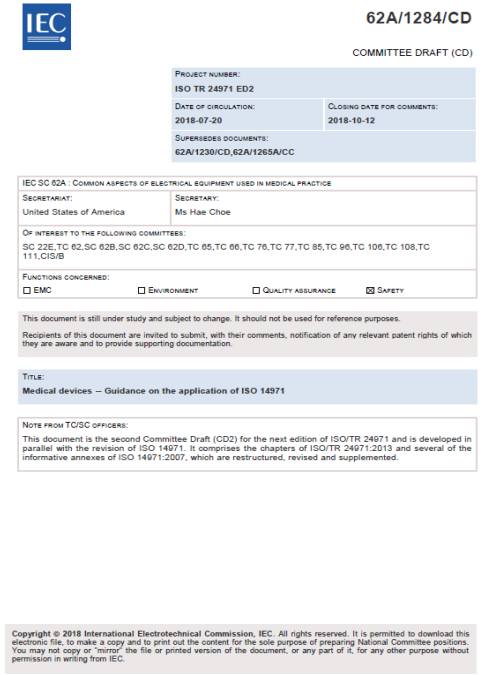
Harmonization with European directives and regulations

- Harmonization will be done by the European Commission

Main changes in ISO/TR CD2 24971



IEC

62A/1284/CD

COMMITTEE DRAFT (CD)

PROJECT NUMBER:
ISO TR 24971 ED2

DATE OF CIRCULATION: 2018-07-20

CLOSING DATE FOR COMMENTS: 2018-10-12

SUPERSEDES DOCUMENTS:
62A/1230/CD,62A/1265A/CC

IEC SC 62A : COMMON ASPECTS OF ELECTRICAL EQUIPMENT USED IN MEDICAL PRACTICE

SECRETARIAT: United States of America

SECRETARY: Ms Hae Choe

OF INTEREST TO THE FOLLOWING COMMITTEES:
SC 22E,TC 62,SC 62B,SC 62C,SC 62D,TC 65,TC 66,TC 76,TC 77,TC 85,TC 96,TC 106,TC 108,TC 111,CIS/B

FUNCTIONS CONCERNED:
☐ EMC ☐ ENVIRONMENT ☐ QUALITY ASSURANCE ☒ SAFETY

This document is still under study and subject to change. It should not be used for reference purposes.

Recipients of this document are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

TITLE:
Medical devices -- Guidance on the application of ISO 14971

NOTE FROM TC/SC OFFICERS:
This document is the second Committee Draft (CD2) for the next edition of ISO/TR 24971 and is developed in parallel with the revision of ISO 14971. It comprises the chapters of ISO/TR 24971:2013 and several of the informative annexes of ISO 14971:2007, which are restructured, revised and supplemented.

- Developed in parallel with the revision of ISO 14971
- Comprises the chapters of ISO/TR 24971:2013
- Includes most annexes of ISO 14971:2007
- Entire document restructured, revised and supplemented.
- NEW Annex on risks related to cybersecurity

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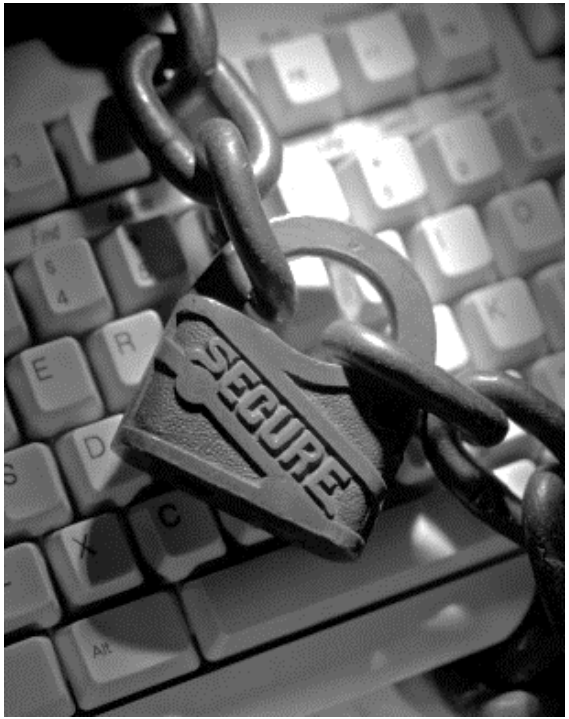
Cybersecurity risks



- Process also suitable for cybersecurity risks
- Correspondence between terms
- Overlapping between health risks and cybersecurity risks

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Main changes: Overview of new structure

CONTENT	
1 Scope	**10** Production and post-production activities
2 Normative references	**Annex A** Identification of hazards and characteristics for safety
3 Terms and definitions	**Annex B** Risk analysis techniques
4 General requirements for risk management	**Annex C** Risk acceptability considerations
5 Risk Analysis	**Annex D** Information for safety and information on residual risk
6 Risk Evaluation	**Annex E** Role of international standards in risk management
7 Risk Control	**Annex F** Guidance on risk related to cybersecurity
8 Evaluation of residual risk	**Annex G** Components and devices designed not using ISO 14971
9 Risk management review	**Annex H** Guidance for in-vitro diagnostic devices

How to fulfill MDR/IVDR risk management requirements?

- Use ISO 14971
- Life-cycle risk management process
- Systematic & regular RMF update
- Train all employees

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Take away notes

- No revolution - Incremental improvements!
- Understand the changes
- Training
- Update your processes & files

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Risk Management – basic course

Objective:

- Based on ISO 14971:2019 and MDR/IVDR
- Fundamentals of risk management
- Tools & analysis methods, hands on examples

Who should attend?

- Personnel who needs basic knowledge
- Personnel who needs to refresh knowledge

When?

- 22-23 October 2019

For more info: www.swedishmedtech.se

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