AI Expert Reviews within the Medical Device Regulation – MDR (EU) 2017/745

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Basel, Intelligent Health 2024

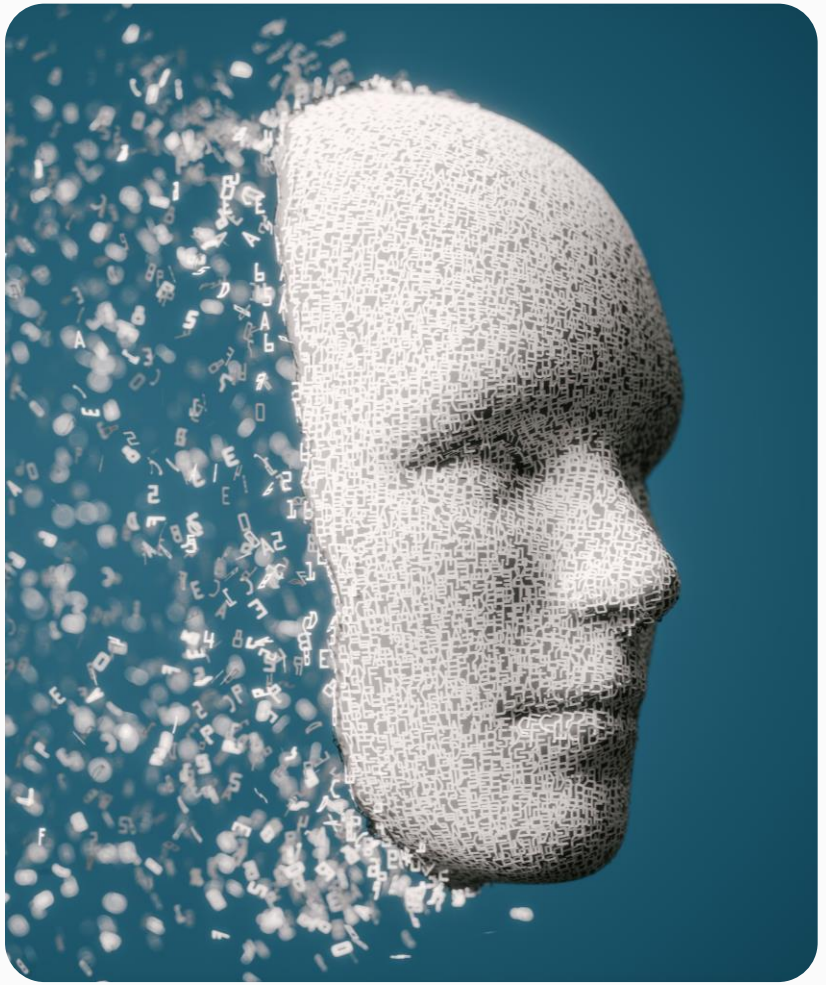
Agenda

MDR Overview
What is the MDR? Why are AI Experts involved?

Technical Review
Process overview, roles, responsibilities and documentation

State of the Art
Legislative requirements and standards

Establishing Best Practice
Position yourself for success



MDR Overview

What is the MDR?

Why are AI Experts involved?

13/09/2024

► B REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 5 April 2017

on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

(Text with EEA relevance)

(OJ L 117, 5.5.2017, p. 1)

Amended by:

		Official Journal		
		No	page	date
► M1	Regulation (EU) 2020/561 of the European Parliament and of the Council of 23 April 2020	L 130	18	24.4.2020
► M2	Commission Delegated Regulation (EU) 2023/502 of 1 December 2022	L 70	1	8.3.2023
► M3	Regulation (EU) 2023/607 of the European Parliament and of the Council of 15 March 2023	L 80	24	20.3.2023

Corrected by:

► C1	Corrigendum, OJ L 117, 3.5.2019, p. 9 (2017/745)
► C2	Corrigendum, OJ L 334, 27.12.2019, p. 165 (2017/745)

Technical Documentation Requirements

MDR

***Article 10** General obligations of manufacturers*

***Article 52** Conformity assessment procedures*

Annex II Technical Documentation

Annex III Technical Documentation on Post-market Surveillance

Annex IX Conformity Assessment Based on a Quality Management System and on Assessment of Technical Documentation

Chapter II Assessment of the Technical Documentation

ANNEX I

GENERAL SAFETY AND PERFORMANCE REQUIREMENTS

CHAPTER 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.

17.2. For devices that incorporate software or for software that are devices in themselves, the software shall be developed and manufactured in accordance with the state of the art taking into account the principles of development life cycle, risk management, including information security, verification and validation.

1	2	3	4	5	6	7	8	9	17.1	17.2	17.3	18.1	18.8	19.1	23.1	23.4

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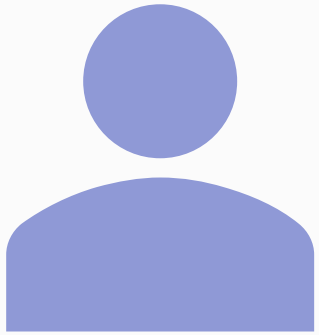
Technical Review

Process overview, roles, responsibilities, and documentation

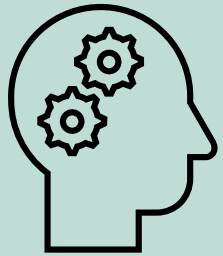
13/09/2024

Medical Devices (MD) Team



Client

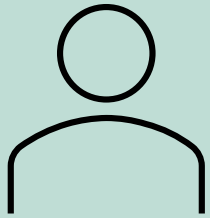
Scheme Manager



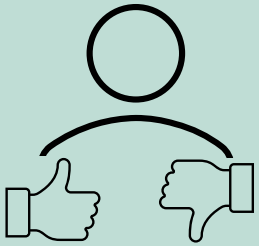
Technical Specialist

Clinical Evaluation Specialist

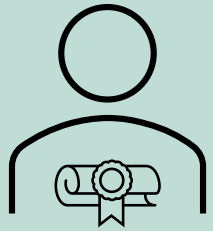
Internal Clinician



Additional Expert

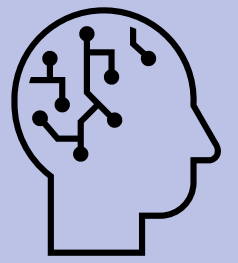


Decision Maker



Certificate Releaser

(AI) Team



AI Expert

Technical Review - Process Overview

Pre-review activity

Client

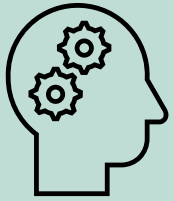
Signed Quotation or Change Notification

Client **MD TS**

Completeness Check

Main review activity

MD TS



Technical Documentation Review

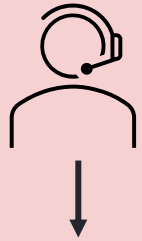
AI Expert

Specialist Assessment Review Form

BSI Review Questions

Review verification activity

Scheme Manager



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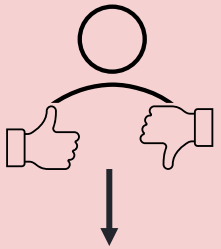

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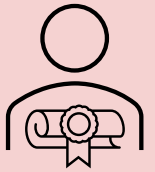


State of the Art

Legislative requirements and standards

13/09/2024

AI reviews

What is "state of the art" in AI for MDR?

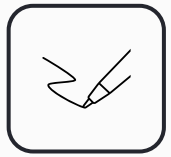
- *Any published standards relevant to AI*
- *Currently standards around JTC/42 from the ISO committee*
- *But may include more from other organisations in the future (e.g. IEEE)*

What steps/assessment areas does an AI review contain?

Currently, the expert reviews look at:

- *How performance is calculated*
- *Any bias in datasets*
- *Trustworthiness and Robustness*
- *ISO 23894 on risk to become a part of the assessment*

Please note:



We are not assessing against the EU AI Act

AI standards

Risk Management and QMS	
ISO/IEC: 23894:2003	**Guidance on risk management**
ISO/IEC 42001:2023	**Management system**
ISO/IEC 42005	AI system impact assessment
ISO/IEC 5338:2023	AI system life cycle processes
ISO/IEC 38507:2022	Governance implications of the use of artificial intelligence by organizations
ISO/IEC 23053:2022	Framework for Artificial Intelligence (AI) Systems Using Machine Learning (ML)

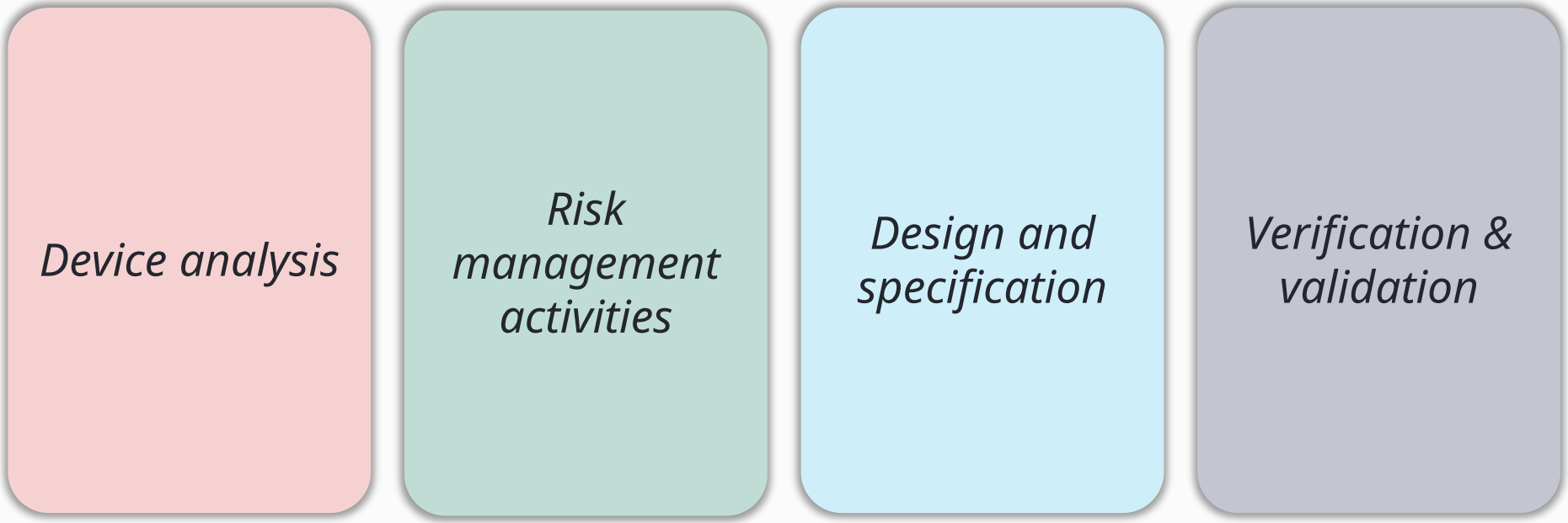
Trustworthiness, Robustness and Responsible AI	
ISO/IEC TR 24028:2022	Overview of trustworthiness in artificial intelligence
ISO/IEC 5339:2024	Guidance for AI applications
ISO/IEC TR 5469:2024	Functional safety and AI systems
ISO/IEC 29197:2015	Evaluation methodology for environmental influence in biometric system performance
ISO/IEC 24029-2:2023	Assessment of the robustness of neural networks - Part 2: Methodology for the use of formal methods
ISO/IEC 24368:2022	Overview of ethical and societal concerns

Security and Privacy	
ISO/IEC TR 27563:2023	Security and privacy in artificial intelligence use cases - Best practices
ISO/IEC 24714:2023	Cross-jurisdictional and societal aspects of biometrics -General guidance
ISO/IEC 27001:2022	Information security management systems
ISO/IEC 27013:2021	Guidance on the integrated implementation of ISO/IEC 27001 and ISO/IEC 20000-1

Data	
ISO/IEC 5259-1:2024	**Data quality for analytics and machine learning (ML) — Part 1: Overview, terminology, and examples**
ISO/IEC FDIS 5259-2	**Data quality for analytics and machine learning (ML) — Part 2: Data quality measures**
ISO/IEC 5259-3:2024	**Data quality for analytics and machine learning (ML) — Part 3: Data quality management requirements and guidelines**
ISO/IEC 5259-4	**Data quality for analytics and machine learning (ML) — Part 4: Data quality process framework**
ISO/IEC DIS 5259-5	**Data quality for analytics and machine learning (ML) — Part 5: Data quality governance framework**
ISO/IEC 8183:2023	Data life cycle framework
ISO/IEC 25024:2015	Systems and software Quality Requirements and Evaluation (SQuaRE) Measurement of data quality

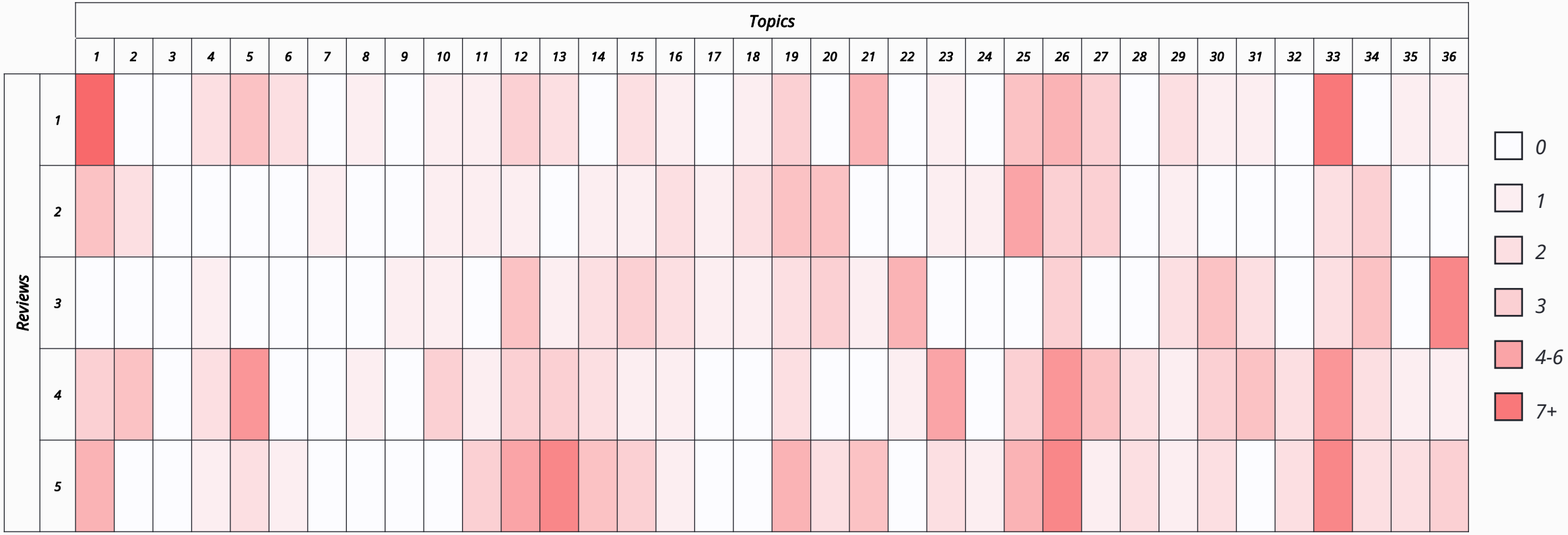
Software Testing	
ISO/IEC TR 29119-11:2020	Software testing Part 11: Guidelines on the testing of AI-based systems
ISO/IEC 25059:2023	**Systems and software Quality Requirements and Evaluation (SQuaRE) Quality model for AI systems**
ISO/IEC 25019:2023 ISO/IEC 25021:2012 ISO/IEC 25041:2012 ISO/IEC 25064:2013	Systems and software Quality Requirements and Evaluation (SQuaRE)
ISO/IEC TR 29119-13:2022	Software testing Part 13: Using the ISO/IEC/IEEE 29119 series in the testing of biometric systems

Main AI review activites



AI expert review analysis

*Analysis of **all topics** investigated during a review – Sample of 5 reviews out of the total*



AI expert review analysis

Analysis of the **macro-categories** investigated during a review

		Description of the AI/ML model(s) incorporated in the system/device	Description of the datasets used in training/testing the AI/ML model(s)	Description of the processes, tools and environments used to train, test and deploy the AI/ML model(s)	AI/ML Risk Management	AI/ML Requirements	AI/ML V&V
Reviews	1	10	9	9	10	15	13
	2	4	3	5	13	15	5
	3	0	1	12	15	5	20
	4	3	14	13	4	23	20
	5	5	4	24	12	20	19

Common questions from clients

Why are we having to undertake an AI review – the AI Act is NOT in force?!

What do we have to provide for the review? What evidence do you expect to see?

How can we be sure that your expert knows enough about our solution to give a fair and objective review?

Do we have to send the AI documents separately or can we send as part of the MDR documents?

Thank you

Q&A