Is the quality of AI-based medical devices warranted by compliance with regulatory requirements?

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AI Quality Summit
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VDE

Agenda

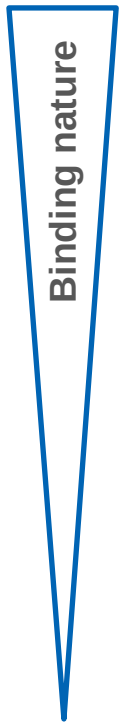
1. Key legislations, standards, and guidances for AI-based medical devices
2. Key regulatory processes ensuring quality of AI-based medical devices

Key legislations, standards, and guidances for AI-based medical devices

Regulatory requirements for AI-based software

What should be considered?

	***Regulations (EU) 2017/745*** *(MDR) and* ***2017/746*** *(IVDR)*
	***German* Medizinprodukterecht-Durchführungsgesetz** *(MPDG)*
	Regulation (EU) 2016/679 *(GDPR)*
	Draft (EU) Artificial Intelligence Act *(AIA) as additional horizontal legislation*
	***Medical Device Standards*** *(no AI medical device standards yet!) and* ***MDCG Guidelines***
	Questionnaire „Artificial Intelligence (AI) in medical devices“ *by German Notified Bodies*
	AI-specific Standards *(selection):* • ***ISO/IEC TR 29119-11:2020*** *Software and systems engin. - Guidelines on the testing of AI-based systems,* • ***ISO/IEC TR 24029-1:2021*** *Artificial Intelligence - Assessment of the robustness of neural networks,* • ***ISO/IEC TR 24028:2020*** *Artificial intelligence - Overview of trustworthiness* • ***ISO/IEC TR 24027:2021*** *Artificial Intelligence - Bias in AI systems and AI-aided decision making etc.* ***Further drafts and new standardization projects*** *by ISO/IEC, AAMI, IEEE etc.*
	***Best-Practices Market Players*** *Google ML, Microsoft AI, Meta AI, IBM Watson etc.*
	Literature Databases *arxiv.org (Artificial Intelligence, Machine Learning), PubMed etc.*



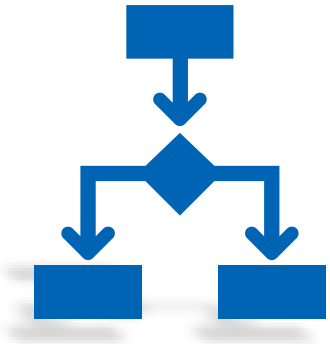
Restrictions of the certifiability

By Interest Group of the Notified Bodies for Medical Devices in Germany (IG-NB)

»***Dynamic AI*** *(AI that continues to learn in the field)* ***is not certifiable*** *in principle, as the system must be verified and validated (among other things, the functionality must be validated against the intended use).«*

»*For* ***static „black box AI“*** *(AI that does not explain how it arrives at a result),* ***regulatory requirements (including 2016/675/EU Articles 22 and 35 (General Data Protection Regulation), 2017/745/EU Annex I No. 17.2, 2017/746/EU Annex I No. 16.2, MDCG 2020-1) set limits on certification****. The possibility of certification requires a review by the Notified Body and is a case-by-case decision.«*

Source: IG-NB Question Catalog “AI in Medical Devices“

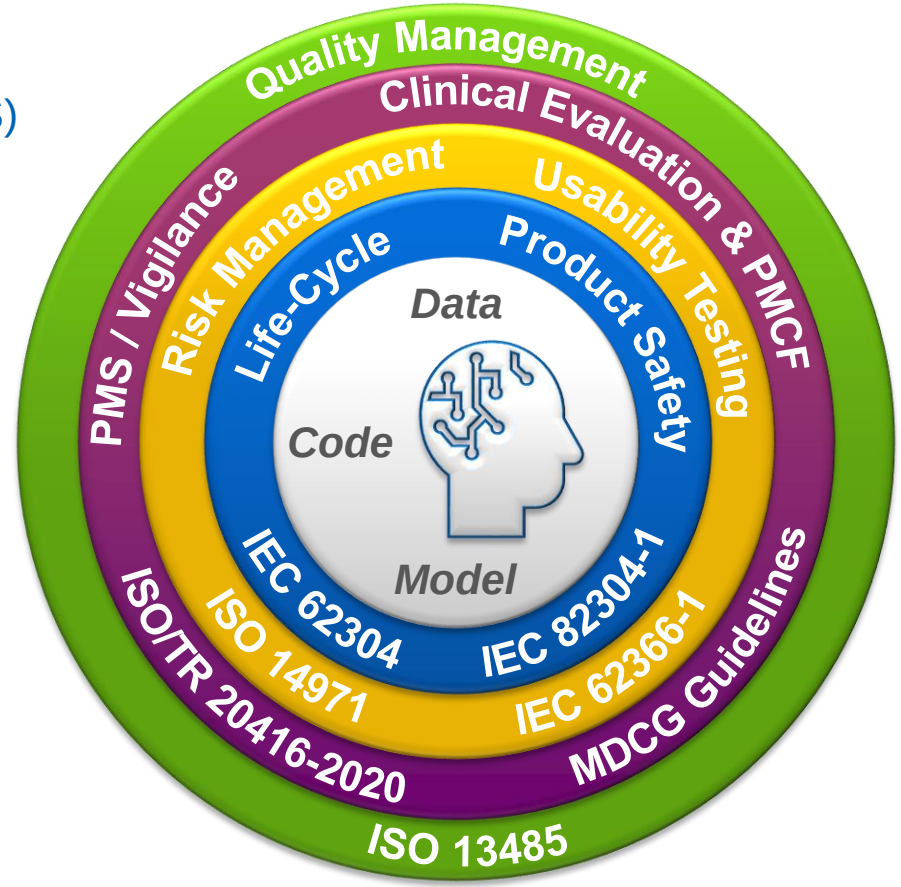


Key regulatory processes ensuring quality of AI-based medical devices

AI model development

Embedded in the manufacturer quality management system (QMS)

»Manufacturer's QMS forms the basis for regulatory compliance of AI-based software with the MDR«

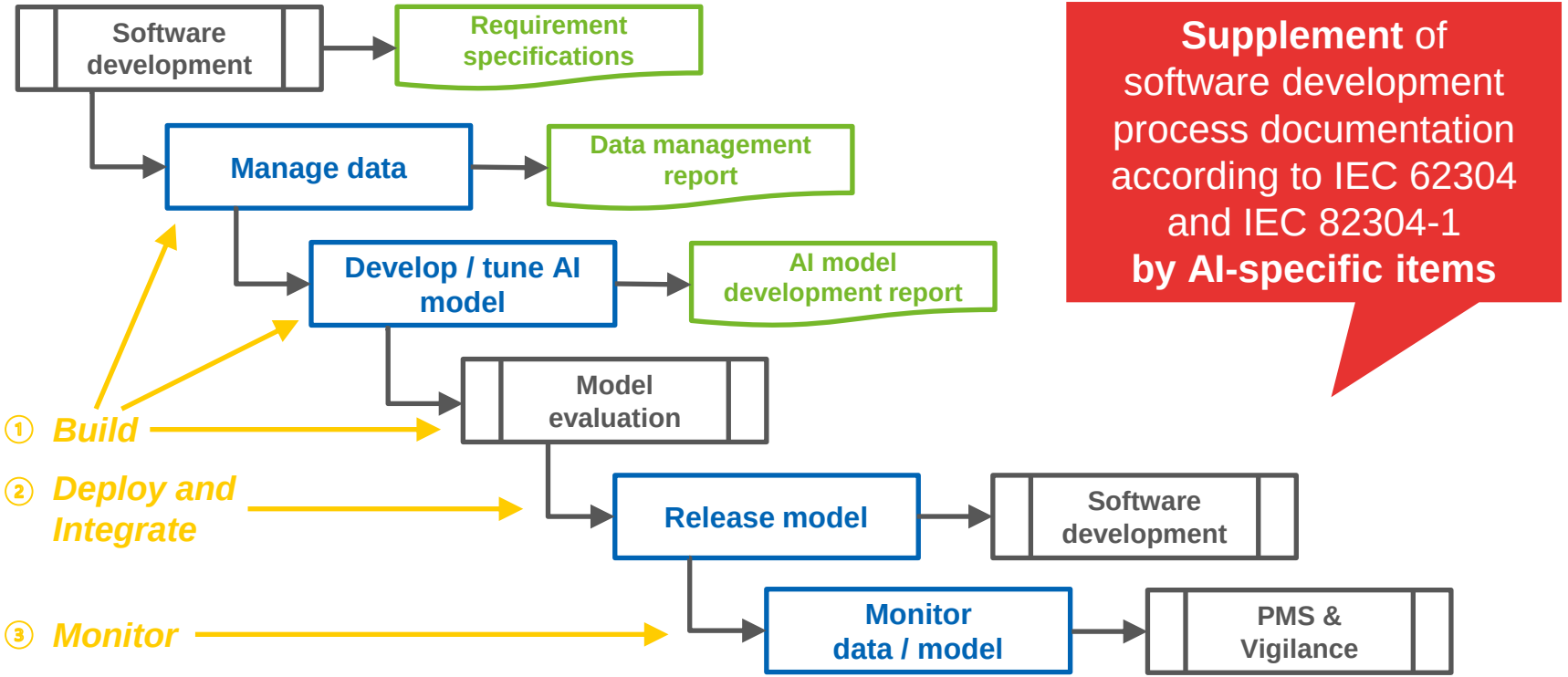


Adaptation of regulatory topics to AI requirements

Affected are various QMS areas

AI model development process

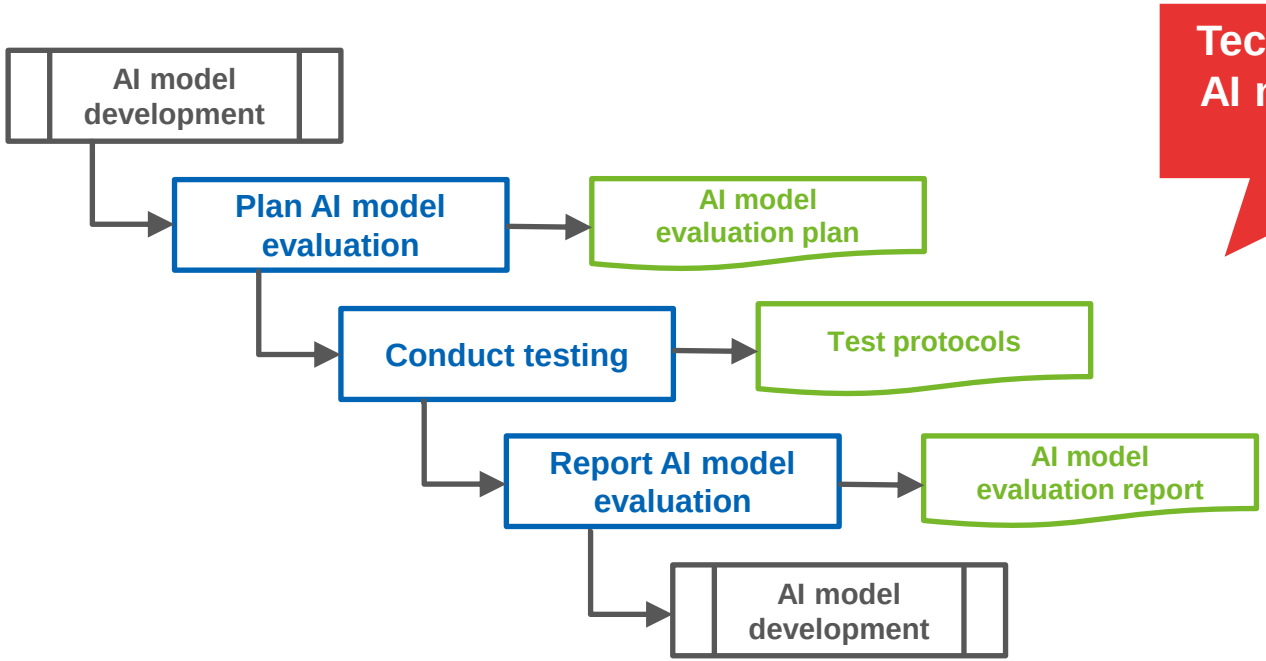
Description AI model development as unit of software system



Supplement of software development process documentation according to IEC 62304 and IEC 82304-1 **by AI-specific items**

AI model evaluation process: process and documents

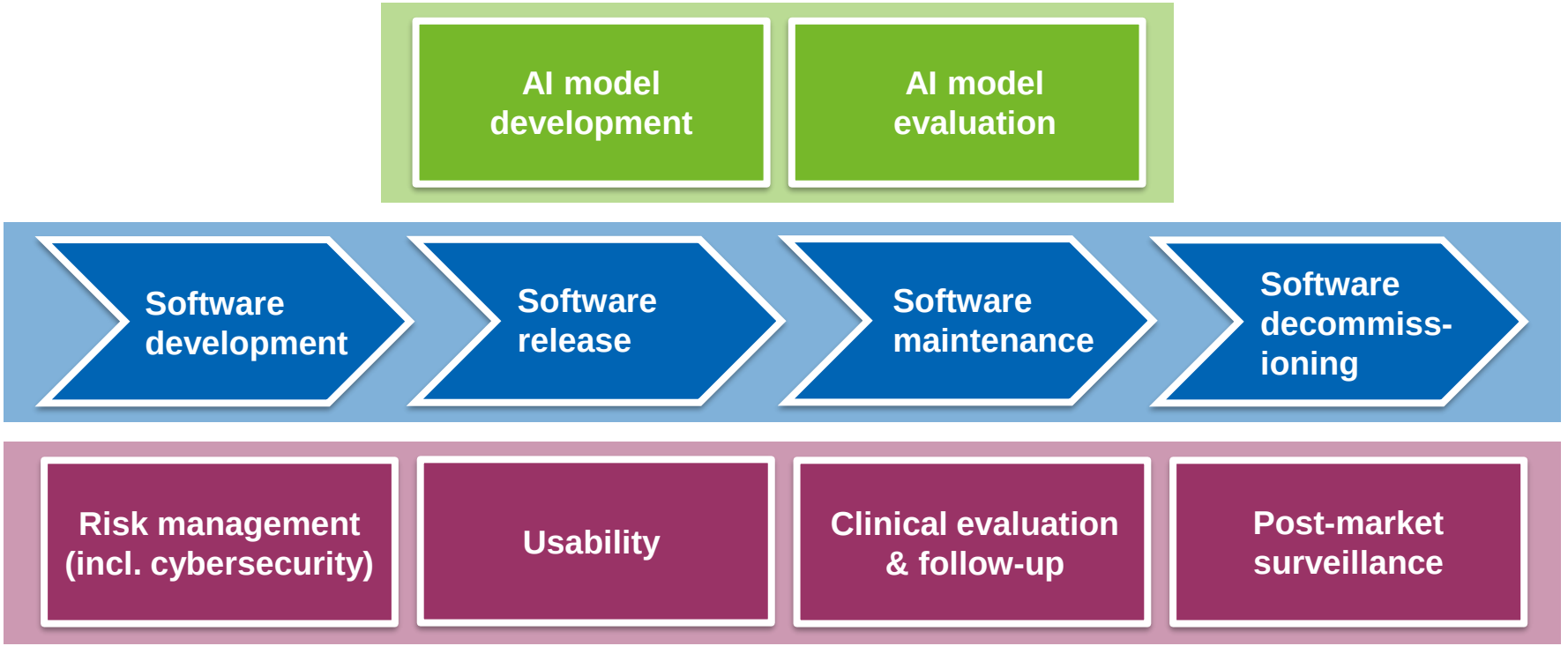
Description of the technical AI model evaluation



Technical evaluation of AI model by testing with separate data set

Summary

AI-specific and other QM processes accompany software life cycle



Summary

Back to the initial question

Is the quality of AI-based medical devices warranted by compliance with regulatory requirements?

Yes, if the medical device manufacturer complies with the regulatory requirements throughout the product life cycle!

VDE Medical Devices and Software

Expertise, Events and Consulting

https://www.vde.com/topics-de/health/beratung

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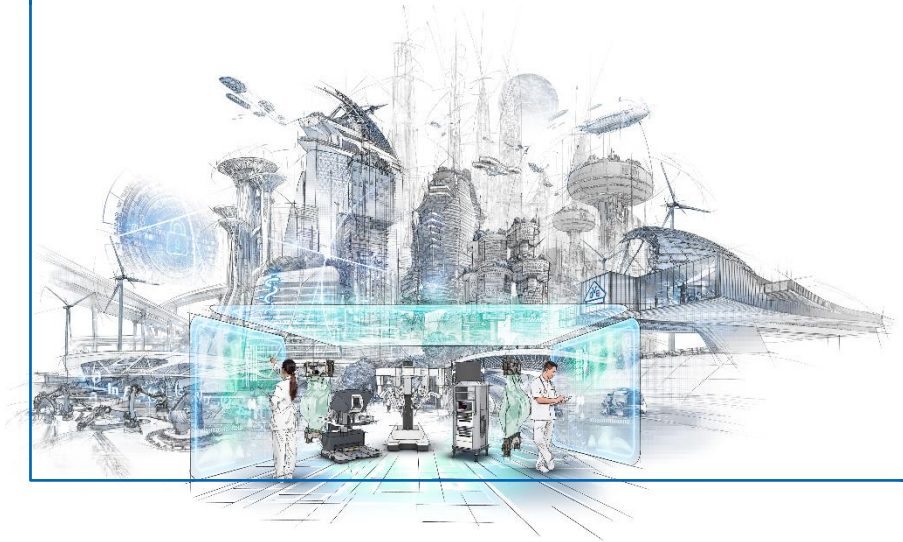

Personal Dr. Prinz works at VDE on the regulatory requirements for medical devices and software. Until 2012, he was employed as group leader and quality manager in the biopharmaceutical industry. Before he served as research associate at the universities of Freiburg and Utrecht.

Company VDE provides expertise, develops standards, offers testing and certification services, and consults on the approval of medical devices and software.

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