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

Thorsten Prinz
AI Quality Summit
02.11.2022
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?

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

1. Software Life Cycle / AI Model Development
2. Risk Management / Cybersecurity
3. Usability Engineering
4. Clinical Evaluation / Follow-up
5. Post-Market Surveillance / Vigilance
AI model development process
Description AI model development as unit of software system

1. **Build**
   - Software development
   - Manage data
   - Develop / tune AI model
   - Model evaluation
   - Release model

2. **Deploy and Integrate**
   - Monitor data / model
   - Software development

3. **Monitor**
   - PMS & Vigilance

**Supplement** of software development process documentation according to IEC 62304 and IEC 82304-1 by AI-specific items
Technical evaluation of AI model by testing with separate data set
Summary

AI-specific and other QM processes accompany software life cycle

- AI model development
- AI model evaluation

- Software development
- Software release
- Software maintenance
- Software decommissioning

- Risk management (incl. cybersecurity)
- Usability
- Clinical evaluation & follow-up
- Post-market surveillance
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

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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.

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