Poster

How to comply with transparency requirements for AI-based medical devices

Thorsten Prinz, VDE Association for Electrical, Electronic & Information Technologies, Offenbach/Main, Germany, thorsten.prinz@vde.com

1

Transparency of AI systems *relates to making the data, features, algorithms, training methods and quality assurance processes available to external inspection by a stakeholder* (ISO/IEC TR 24028)

2

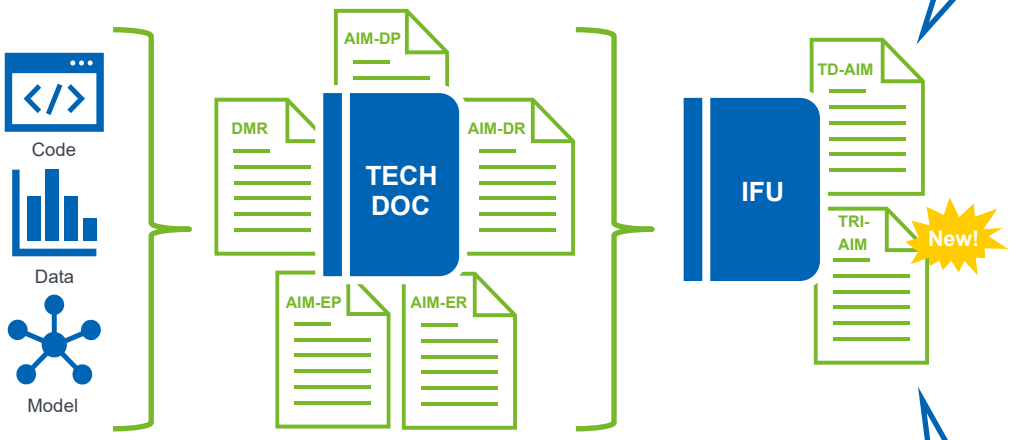
High-risk AI systems *shall be designed and developed in such a way as to ensure that their operation is sufficiently transparent […] (Art. 13 EU AI Act)*

3

Content "AI documents"
Data management, AI model development and evaluation

4

Content "Technical Description"
Technical characteristics of AI model, clinical benefits, and residual risks



Abbreviations: AIM = AI Model, DP = Development Plan, DMR = Data Management Report, DP = Development Report, EP = Evaluation Plan, ER = Evaluation Report, IFU= Instructions For Use, TECH DOC = Technical Documentation, TD = Technical Description, TRI = Transparency Information

5

Content "Transparency Information"
General purpose and functioning, rational for using AI technology, safety / performance, currentness, general risks, official product certifications, and limitations

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