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| **ITU-T Focus Group on AI for Health** |
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| **DOCUMENT** |
| **Source:** | Johner Institute (Germany) |
| **Title:** | AI guideline for medical devices |
| **Purpose:** | Discussion |
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| **Abstract:** | This AI guideline / checklist is supposed to serve medical device manufacturers, notified bodies and authorities to* gain a common understanding of **AI related requirements** and **best practices**
* guide the **development, verification and validation** as well as the **post-market surveillance** of medical devices that incorporate machine learning algorithms
* guide the compilation and the **review** of the respective **technical documentation**
* guide the adaptation of **SOPs, process descriptions and work instructions** as well as compliance checks e.g. as part of **audits**

The guideline is available on github (<https://github.com/johner-institut/ai-guideline>) as well as document [FGAI4H-H-034-A01](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/docs/FGAI4H-H-034-A01.pdf). |

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