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| ITU Logo | INTERNATIONAL TELECOMMUNICATION UNION  **TELECOMMUNICATION STANDARDIZATION SECTOR**  STUDY PERIOD 2017-2020 | | FG-AI4H-H-034 | |
| **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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