ISO/TS 24971-2:2026-06 (E)

Medical devices - Guidance on the application of ISO 14971 - Part 2: Machine learning in artificial intelligence

Contents

Page

Foreword ... **iv**

Introduction ... **v**

1 Scope ... **1**

2 Normative references ... **1**

3 Terms and definitions ... **1**

4 General requirements for *risk management* system ... **4**
4.1 *Risk management process* ... 4
4.2 Management responsibilities ... 4
4.3 Competence of personnel ... 4
4.4 *Risk management* plan ... 5
4.5 *Risk management file* ... 5

5 *Risk analysis* ... **5**
5.1 *Risk analysis process* ... 5
5.2 *Intended use* and *reasonably foreseeable misuse* ... 6
5.3 Identification of characteristics related to *safety* ... 6
5.4 Identification of *hazards* and *hazardous situations* ... 6
5.5 *Risk estimation* ... 6

6 *Risk evaluation* ... **6**

7 *Risk control* ... **7**
7.1 *Risk control* option analysis ... 7
7.2 Implementation of *risk control* measures ... 7
7.3 *Residual risk* evaluation and subsequent steps ... 8

8 Evaluation of overall *residual risk* ... **8**
8.1 General considerations for *MLMD* ... 8
8.2 Disclosure of significant *residual risks* ... 8

9 *Risk management* review ... **9**

10 Production and *post-production* activities ... **9**
10.1 General ... 9
10.2 Information collection ... 10
10.3 Information review ... 10
10.4 Actions ... 10

Annex A (informative) **Explanation of *bias*** ... **12**

Annex B (informative) **Examples of *hazards* and *hazardous situations*** ... **15**

Annex C (informative) **Identification of *hazards* and characteristics related to *safety*** ... **20**

Annex D (informative) **Considerations for *MLMD* having a level of autonomy** ... **29**

Bibliography ... **31**