

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 <i>risk management</i> system.....	4
4.1 <i>Risk management process</i>	4
4.2 Management responsibilities.....	4
4.3 Competence of personnel.....	4
4.4 <i>Risk management plan</i>	5
4.5 <i>Risk management file</i>	5
5 <i>Risk analysis</i>.....	5
5.1 <i>Risk analysis process</i>	5
5.2 <i>Intended use and reasonably foreseeable misuse</i>	6
5.3 Identification of characteristics related to <i>safety</i>	6
5.4 Identification of <i>hazards</i> and <i>hazardous situations</i>	6
5.5 <i>Risk estimation</i>	6
6 <i>Risk evaluation</i>.....	6
7 <i>Risk control</i>.....	7
7.1 <i>Risk control</i> option analysis.....	7
7.2 Implementation of <i>risk control</i> measures.....	7
7.3 <i>Residual risk</i> evaluation and subsequent steps.....	8
8 Evaluation of overall <i>residual risk</i>.....	8
8.1 General considerations for <i>MLMD</i>	8
8.2 Disclosure of significant <i>residual risks</i>	8
9 <i>Risk management</i> review.....	9
10 Production and <i>post-production</i> 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 <i>bias</i>.....	12
Annex B (informative) Examples of <i>hazards</i> and <i>hazardous situations</i>.....	15
Annex C (informative) Identification of <i>hazards</i> and characteristics related to <i>safety</i>.....	20
Annex D (informative) Considerations for <i>MLMD</i> having a level of autonomy.....	29
Bibliography.....	31