

DIN EN ISO 14971:2020-07 (E)

Medical devices - Application of risk management to medical devices (ISO 14971:2019)

| Contents | Page |
|--|------|
| European foreword | 3 |
| Foreword | 4 |
| Introduction | 6 |
| 1 Scope | 8 |
| 2 Normative references | 8 |
| 3 Terms and definitions | 8 |
| 4 General requirements for <i>risk management system</i> | 14 |
| 4.1 <i>Risk management process</i> | 14 |
| 4.2 Management responsibilities | 15 |
| 4.3 Competence of personnel | 16 |
| 4.4 <i>Risk management plan</i> | 16 |
| 4.5 <i>Risk management file</i> | 17 |
| 5 <i>Risk analysis</i> | 17 |
| 5.1 <i>Risk analysis process</i> | 17 |
| 5.2 <i>Intended use</i> and <i>reasonably foreseeable misuse</i> | 17 |
| 5.3 Identification of characteristics related to <i>safety</i> | 18 |
| 5.4 Identification of <i>hazards</i> and <i>hazardous situations</i> | 18 |
| 5.5 <i>Risk estimation</i> | 18 |
| 6 <i>Risk evaluation</i> | 19 |
| 7 <i>Risk control</i> | 19 |
| 7.1 <i>Risk control</i> option analysis | 19 |
| 7.2 Implementation of <i>risk control</i> measures | 20 |
| 7.3 <i>Residual risk</i> evaluation | 20 |
| 7.4 <i>Benefit-risk</i> analysis | 21 |
| 7.5 <i>Risks</i> arising from <i>risk control</i> measures | 21 |
| 7.6 Completeness of <i>risk control</i> | 21 |
| 8 Evaluation of overall <i>residual risk</i> | 21 |
| 9 <i>Risk management review</i> | 22 |
| 10 Production and <i>post-production</i> activities | 22 |
| 10.1 General | 22 |
| 10.2 Information collection | 22 |
| 10.3 Information review | 23 |
| 10.4 Actions | 23 |
| Annex A (informative) Rationale for requirements | 24 |
| Annex B (informative) <i>Risk management process for medical devices</i> | 33 |
| Annex C (informative) Fundamental <i>risk concepts</i> | 37 |
| Bibliography | 43 |