

# ISO 14971:2019-12 (E)

## Medical devices - Application of risk management to medical devices

---

<b>Contents</b>		<b>Page</b>
Foreword .....		iv
Introduction .....		vi
1	Scope .....	1
2	Normative references .....	1
3	Terms and definitions .....	1
4	General requirements for risk management system .....	7
4.1	Risk management process .....	7
4.2	Management responsibilities .....	8
4.3	Competence of personnel .....	9
4.4	Risk management plan .....	9
4.5	Risk management file .....	10
5	Risk analysis .....	10
5.1	Risk analysis process .....	10
5.2	Intended use and reasonably foreseeable misuse .....	10
5.3	Identification of characteristics related to safety .....	11
5.4	Identification of hazards and hazardous situations .....	11
5.5	Risk estimation .....	11
6	Risk evaluation .....	12
7	Risk control .....	12
7.1	Risk control option analysis .....	12
7.2	Implementation of risk control measures .....	13
7.3	Residual risk evaluation .....	13
7.4	Benefit-risk analysis .....	14
7.5	Risks arising from risk control measures .....	14
7.6	Completeness of risk control .....	14
8	Evaluation of overall residual risk .....	14
9	Risk management review .....	15
10	Production and post-production activities .....	15
10.1	General .....	15
10.2	Information collection .....	15
10.3	Information review .....	16
10.4	Actions .....	16
Annex A (informative)	Rationale for requirements .....	17
Annex B (informative)	Risk management process for medical devices .....	26
Annex C (informative)	Fundamental risk concepts .....	30
Bibliography .....		36