

Contents

Page

Foreword.....	iv
Introduction	v
1 Scope	1
2 Terms and definitions	1
3 General requirements for risk management	4
3.1 National or regional regulatory requirements	4
3.2 Risk management process	4
3.3 Management responsibilities	4
3.4 Qualification of personnel	5
3.5 Risk management plan.....	5
3.6 Risk management file.....	6
4 Risk analysis (Steps 1, 2 and 3 of Figure 2)	6
4.1 Risk analysis procedure	6
4.2 Intended use/intended purpose and identification of characteristics related to the safety of the medical device (Step 1)	6
4.3 Identification of known or foreseeable hazards (Step 2)	8
4.4 Estimation of the risk(s) for each hazard (Step 3)	8
5 Risk evaluation (Step 4).....	9
6 Risk control (Steps 5 to 10)	9
6.1 Risk reduction	9
6.2 Option analysis (Step 5)	9
6.3 Implementation of risk control measure(s) (Step 6)	9
6.4 Residual risk evaluation (Step 7).....	10
6.5 Risk/benefit analysis (Step 8)	10
6.6 Other generated hazards (Step 9).....	10
6.7 Completeness of risk evaluation (Step 10).....	10
7 Overall residual risk evaluation (Step 11).....	10
8 Risk management report (Step 12).....	10
9 Post-production information (Step 13)	11
Annex A (informative) Questions that can be used to identify medical device characteristics that could impact on safety.....	12
Annex B (informative) Guidance on risk analysis for <i>in vitro</i> diagnostic medical devices.....	16
Annex C (informative) Guidance on risk analysis procedure for toxicological hazards	17
Annex D (informative) Examples of possible hazards and contributing factors associated with medical devices.....	19
Annex E (informative) Risk concepts applied to medical devices	23
Annex F (informative) Information on risk analysis techniques	28
Annex G (informative) Other standards that contain information related to the elements of risk management described in this International Standard.....	30
Bibliography	31