

DIN EN ISO 13485:2010-01 (E)

Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2003 + Cor. 1:2009) (includes Corrigendum AC:2009)

Contents

Page

Foreword	2
0 Introduction	5
0.1 General	5
0.2 Process approach	5
0.3 Relationship with other standards	5
0.4 Compatibility with other management systems	6
1 Scope	6
1.1 General	6
1.2 Application	6
2 Normative references	7
3 Terms and definitions	7
4 Quality management system	9
4.1 General requirements	9
4.2 Documentation requirements	9
5 Management responsibility	11
5.1 Management commitment	11
5.2 Customer focus	11
5.3 Quality policy	11
5.4 Planning	12
5.5 Responsibility, authority and communication	12
5.6 Management review	13
6 Resource management	13
6.1 Provision of resources	13
6.2 Human resources	14
6.3 Infrastructure	14
6.4 Work environment	14
7 Product realization	15
7.1 Planning of product realization	15
7.2 Customer-related processes	15
7.3 Design and development	16
7.4 Purchasing	18
7.5 Production and service provision	19
7.6 Control of monitoring and measuring devices	22
8 Measurement, analysis and improvement	22
8.1 General	22
8.2 Monitoring and measurement	23
8.3 Control of nonconforming product	24
8.4 Analysis of data	24
8.5 Improvement	25
Annex A (informative) Correspondence between ISO 13485:2003 and ISO 13485:1996	26

Annex B (informative) Explanation of differences between ISO 13485:2003 and ISO 9001:2000	30
Annex ZA (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 90/385/EEC	62
Annex ZB (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC	63
Annex ZC (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 98/79/EC	64
Bibliography	65