

ISO 13485:2003-07 (E)

Medical devices - Quality management systems - Requirements for regulatory purposes

Contents

Page

Foreword	iv
0 Introduction	v
0.1 General	v
0.2 Process approach	v
0.3 Relationship with other standards	vi
0.4 Compatibility with other management systems	vi
1 Scope	1
1.1 General	1
1.2 Application	1
2 Normative references	2
3 Terms and definitions	2
4 Quality management system	4
4.1 General requirements	4
4.2 Documentation requirements	4
5 Management responsibility	6
5.1 Management commitment	6
5.2 Customer focus	6
5.3 Quality policy	6
5.4 Planning	7
5.5 Responsibility, authority and communication	7
5.6 Management review	8
6 Resource management	8
6.1 Provision of resources	8
6.2 Human resources	9
6.3 Infrastructure	9
6.4 Work environment	9
7 Product realization	10
7.1 Planning of product realization	10
7.2 Customer-related processes	10
7.3 Design and development	11
7.4 Purchasing	13
7.5 Production and service provision	14
7.6 Control of monitoring and measuring devices	17
8 Measurement, analysis and improvement	17
8.1 General	17
8.2 Monitoring and measurement	18
8.3 Control of nonconforming product	19
8.4 Analysis of data	19
8.5 Improvement	20
Bibliography	57