DIN EN ISO 13485:2021-12 (E)

Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016) (includes Corrigendum:2018)

Contents

Page

[A11] European foreword to Amendment [A11] ... **4**

European foreword ... **5**

Annex ZA (informative) **[A11] Relationship between this European standard and the requirements of Regulation (EU) 2017/745 aimed to be covered [A11]** ... **6**

Annex ZB (informative) **[A11] Relationship between this European standard and the requirements of Regulation (EU) 2017/746 aimed to be covered [A11]** ... **18**

Foreword ... **30**

Introduction ... **31**

1 Scope ... **34**

2 Normative references ... **34**

3 Terms and definitions ... **34**

4 Quality management system ... **39**
4.1 General requirements ... 39
4.2 Documentation requirements ... 40
4.2.1 General ... 40
4.2.2 Quality manual ... 40
4.2.3 Medical device file ... 40
4.2.4 Control of documents ... 41
4.2.5 Control of records ... 41

5 Management responsibility ... **42**
5.1 Management commitment ... 42
5.2 Customer focus ... 42
5.3 Quality policy ... 42
5.4 Planning ... 42
5.4.1 Quality objectives ... 42
5.4.2 Quality management system planning ... 42
5.5 Responsibility, authority and communication ... 43
5.5.1 Responsibility and authority ... 43
5.5.2 Management representative ... 43
5.5.3 Internal communication ... 43
5.6 Management review ... 43
5.6.1 General ... 43
5.6.2 Review input ... 43
5.6.3 Review output ... 44

6 Resource management ... **44**
6.1 Provision of resources ... 44
6.2 Human resources ... 44
6.3 Infrastructure ... 45
6.4 Work environment and contamination control ... 45
6.4.1 Work environment ... 45
6.4.2 Contamination control ... 45

7 Product realization ... **45**
7.1 Planning of product realization ... 45
7.2 Customer-related processes ... 46
7.2.1 Determination of requirements related to product ... 46
7.2.2 Review of requirements related to product ... 46
7.2.3 Communication ... 47

7.3 Design and development 47
7.3.1 General 47
7.3.2 Design and development planning 47
7.3.3 Design and development inputs 47
7.3.4 Design and development outputs 48
7.3.5 Design and development review 48
7.3.6 Design and development verification 48
7.3.7 Design and development validation 48
7.3.8 Design and development transfer 49
7.3.9 Control of design and development changes 49
7.3.10 Design and development files 49
7.4 Purchasing 50
7.4.1 Purchasing process 50
7.4.2 Purchasing information 50
7.4.3 Verification of purchased product 50
7.5 Production and service provision 51
7.5.1 Control of production and service provision 51
7.5.2 Cleanliness of product 51
7.5.3 Installation activities 51
7.5.4 Servicing activities 52
7.5.5 Particular requirements for sterile medical devices 52
7.5.6 Validation of processes for production and service provision 52
7.5.7 Particular requirements for validation of processes for sterilization and sterile barrier systems 52
7.5.8 Identification 53
7.5.9 Traceability 53
7.5.10 Customer property 53
7.5.11 Preservation of product 53
7.6 Control of monitoring and measuring equipment 54
8 Measurement, analysis and improvement 55
8.1 General 55
8.2 Monitoring and measurement 55
8.2.1 Feedback 55
8.2.2 Complaint handling 55
8.2.3 Reporting to regulatory authorities 56
8.2.4 Internal audit 56
8.2.5 Monitoring and measurement of processes 56
8.2.6 Monitoring and measurement of product 56
8.3 Control of nonconforming product 57
8.3.1 General 57
8.3.2 Actions in response to nonconforming product detected before delivery 57
8.3.3 Actions in response to nonconforming product detected after delivery 57
8.3.4 Rework 57
8.4 Analysis of data 57
8.5 Improvement 58
8.5.1 General 58
8.5.2 Corrective action 58
8.5.3 Preventive action 58
Annex A (informative) **Comparison of content between ISO 13485:2003 and ISO 13485:2016 60**
Annex B (informative) **Correspondence between ISO 13485:2016 and ISO 9001:2015 63**
Bibliography 69