

DIN EN ISO 13485:2021-12 (E)

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

Contents		Page
Annex ZA (informative) Relationship between this European standard and the requirements of Regulation (EU) 2017/745 aimed to be covered	4	4
European foreword		5
Annex ZA (informative) Relationship between this European standard and the requirements of Regulation (EU) 2017/745 aimed to be covered	6	6
Annex ZB (informative) Relationship between this European standard and the requirements of Regulation (EU) 2017/746 aimed to be covered	18	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