

# DIN EN ISO 13485:2021-12 (E)

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

---

### Contents

Page

<b>Annex ZA</b> (informative) <b>Relationship between this European standard and the requirements of Regulation (EU) 2017/745 aimed to be covered</b>	<b>4</b>
<b>European foreword</b>	<b>5</b>
<b>Annex ZB</b> (informative) <b>Relationship between this European standard and the requirements of Regulation (EU) 2017/746 aimed to be covered</b>	<b>18</b>
<b>Foreword</b>	<b>30</b>
<b>Introduction</b>	<b>31</b>
<b>1 Scope</b>	<b>34</b>
<b>2 Normative references</b>	<b>34</b>
<b>3 Terms and definitions</b>	<b>34</b>
<b>4 Quality management system</b>	<b>39</b>
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
<b>5 Management responsibility</b>	<b>42</b>
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
<b>6 Resource management</b>	<b>44</b>
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
<b>7 Product realization</b>	<b>45</b>
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
<b>8</b>	<b>Measurement, analysis and improvement.....</b>	<b>55</b>
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
	<b>Annex A (informative) Comparison of content between ISO 13485:2003 and ISO 13485:2016.....</b>	<b>60</b>
	<b>Annex B (informative) Correspondence between ISO 13485:2016 and ISO 9001:2015.....</b>	<b>63</b>
	<b>Bibliography.....</b>	<b>69</b>