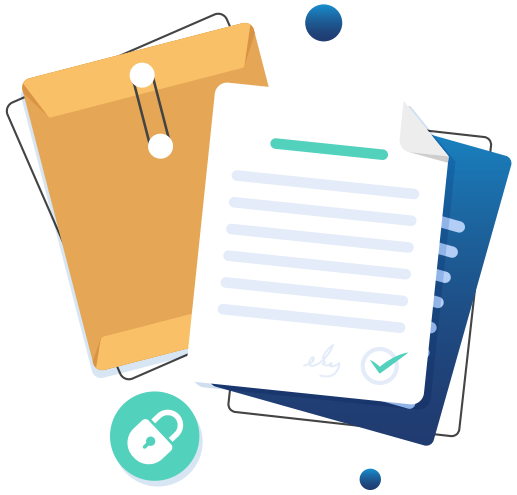
Automate

ISO 13485 Compliance with Effivity

- ✓ Simple
- ✓ Employee-Friendly
- ✓ Audit Ready
- ✓ 24x7 Accessible



ISO 13485:2016

Mandatory Documentation Requirements & Records

Mandatory Documents

All below mandatory documents can be created using Documented information module of Effivity. An organization can use their own procedures but if required Effivity can provide these procedures to our Large enterprise plan customers with biennial subscription.

S.No	Mandatory Documents	Clause of ISO 13485:2016
1.	Document the role(s) undertaken by the organization	4.1.1
2.	Written quality agreements with outsource partners	4.1.5
3.	Procedure for the validation of the application of Computer software	4.1.6, 7.5.6, 7.6
4.	Quality manual	4.2.1
5.	Quality policy	4.2.1
6.	Quality objectives	4.2.1
7.	Procedure for document control	4.2.4
8.	Procedure for record control	4.2.5
9.	Responsibilities and authorities	5.5.1
10.	Procedure for management review	5.6.1
11.	Procedure for competence, training and awareness	6.2
12.	Requirements for the infrastructure	6.3
13.	Requirements for the maintenance activities	6.3
14.	Requirements for the work environment	6.4.1
15.	Procedure to monitor and control the work environment	6.4.1

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Mandatory Documentation Requirements & Records

S.No	Mandatory Documents	Clause of ISO 13485:2016
16.	Requirements for health, cleanliness and clothing of personnel	6.4.1
17.	Arrangements for the control of contaminated or potentially contaminated product	6.4.2
18.	Requirements for control of sterile medical device contamination	6.4.2
19.	Processes for risk management in product realization	7.1
20.	Arrangements for communicating with customers	7.2.3
21.	Procedure for design and development	7.3.1
22.	Procedure for purchasing	7.4.1
23.	Procedure and methods for the control of production	7.5.1
24.	Requirements for cleanliness of product	7.5.2
25.	Requirements for medical device installation and acceptance criteria for verification of installation	7.5.3
26.	Procedure for servicing activities of medical devices	7.5.4
27.	Procedures for validation of processes	7.5.6
28.	Procedure for the validation of processes for sterilization	7.5.7
29.	Procedure for product identification	7.5.8
30.	Procedure for traceability	7.5.9.1
31.	Procedure for preserving the conformity of product	7.5.11
32.	Procedure for monitoring and measuring equipment	7.6
23.	Procedure for customer feedback gathering	8.2.1
34.	Procedure for complaint handling	8.2.2
35.	Procedure for internal audit	8.2.4
36.	Procedure for control of nonconforming product	8.3.1
37.	Procedure for issuing advisory notices	8.3.3
38.	Procedure for rework	8.3.4
39.	Procedure for analysis of data	8.4
40.	Procedure for corrective actions	8.5.2
41.	Procedure for preventive actions	8.5.3

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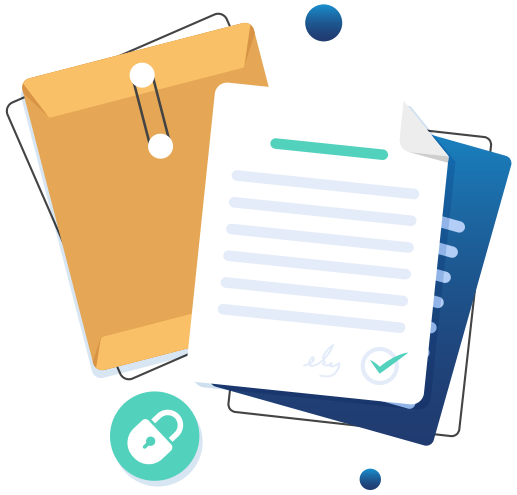

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Mandatory Documentation Requirements & Records

Mandatory Records

Effivity provides online compliance with more than 75% mandatory records requirements. Specific customization is possible for our large enterprises subscription clients.

Note: The text in green indocates the availabilty of this feature in Effivity

S.No	Mandatory Documents	Clause of ISO 13485:2016
1.	Records of software validation activities	4.1.6, 7.6
2.	Medical device file	4.2.3
3.	Records of management review	5.6.1
4.	Records of education, training. skills and experience	6.2
5.	Records of the maintenance activities	6.3
6.	Records of risk management activities	7.1
7.	Outputs of product realization planning	7.1
8.	Records of the results and actions arising from review of requirements related to product	7.2.2
9.	Records of product requirements changes	7.2.2
10.	Design and development planning documents	7.3.2
11.	Design and development inputs	7.3.3
12.	Design and development outputs	7.3.4
13.	Records of design and development review	7.3.5
14.	Records of the results and conclusions of the design and development verification	7.3.6
15.	Design and development validation plans	7.3.7

ISO 13485:2016

Mandatory Documentation Requirements & Records

S.No	Mandatory Documents	Clause of ISO 13485:2016
16.	Records of the results and conclusion of design and development validation	7.3.7
17.	Results and conclusions of the design and development transfer	7.3.8
18.	Records of design and development changes	7.3.9
19.	Design and development file	7.3.10
20.	Records of the results of evaluation, selection, monitoring and re-evaluation of supplier	7.4.1
21.	Records of the purchased product verification	7.4.3
22.	Record for each medical device or batch of medical devices	7.5.1
23.	Records of medical device installation and verification of installation	7.5.3
24.	Records of servicing activities	7.5.4
25.	Records of the sterilization process parameters	7.5.5
26.	Records of the results and conclusion of validation	7.5.6
27.	Records of the results and conclusion of sterile medical device validation	7.5.7
28.	Records of traceability	7.5.9.2
29.	Records of the name and address of the shipping package consignee	7.5.9.2
30.	Report to the customer about changes on his property	7.5.10
31.	Records of the results of calibration and verification of monitoring and measuring equipment	7.6
32.	Customer feedback report	8.2.1
23.	Complaint handling records	8.2.2
34.	Records of reporting to regulatory authorities	8.2.3
35.	Internal audit plan	8.2.4
36.	Internal audit report	8.2.4
37.	Evidence of conformity of products with the acceptance criteria	8.2.6
38.	Identity of the person authorizing release of product	8.2.6
39.	Identity of personnel performing any inspection or testing of implantable medical devices	8.2.6
40.	Record of nonconformity	8.3.1

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Mandatory Documentation Requirements & Records

S.No	Mandatory Documents	Clause of ISO 13485:2016
41.	Records of the product acceptance by concession and the identity of the person authorizing the concession	8.3.2
42.	Records of actions relating to the issuance of advisory notices	8.3.3
43.	Records of rework	8.3.4
44.	Records of the results of data analyses	8.4
45.	Records of corrective actions	8.5.2
46.	Records of preventive actions	8.5.3

In addition to this Effivity provides online consulting and implementation assistance to subscribers.