

## List of Mandatory Procedures

#	ISO 13485 Clause No.	SOP NO.	Name of the PROCEDURE
1.	4.1	QMS-SOP-01	Control of Out sourced Activities
2.	4.2.3	QMS-SOP-02	Control of Documents
3.	4.2.4	QMS-SOP-03	Control of records
4.	5.66.3	QMS-SOP-04	Management Review
5.	6.2.2	QMS-SOP-05	Training
6.	6.3	QMS-SOP-06	Maintenance Activities
7.	6.4	QMS-SOP-07	Health, cleanliness and clothing if come in contact with the product can affect it
8.	6.4	QMS-SOP-08	Work environment conditions, monitoring and control
9.	6.4	QMS-SOP-09	Control of contaminated or potential contaminated products to prevent product contamination
10.	7.1	QMS-SOP-10	Risk Management
11.	7.3.1	QMS-SOP-11	Design and development
12.	7.4.1	QMS-SOP-12	Purchasing process
13.	7.5.1.2.1	QMS-SOP-13	Product cleanliness
14.	7.5.1.2.2	QMS-SOP-14	Installation activities
15.	7.5.1.2.3	QMS-SOP-15	Servicing activities
16.	7.5.2.1	QMS-SOP-16	Validation of the application of the computer S/W
17.	7.5.2.2	QMS-SOP-17	Sterilization process validation
18.	7.5.3.1	QMS-SOP-18	Product identification
19.	7.5.3.1	QMS-SOP-19	Product return identification from normal production
20.	7.5.3.2	QMS-SOP-20	Product traceability
21.	7.5.5	QMS-SOP-21	Product preservation
22.	7.5.5	QMS-SOP-22	Control of limited shelf life products
23.	7.6	QMS-SOP-23	Control of monitoring and measuring equipment
24.	8.2.1	QMS-SOP-24	Feedback system (including customer complaint)
25.	8.2.1	QMS-SOP-25	Post-production phase experience
26.	8.2.1	QMS-SOP-26	Post Market Clinical follow up
27.	8.2.1	QMS-SOP-27	Clinical Evaluation
28.	8.2.2	QMS-SOP-28	Internal audit
29.	8.2.4.1	QMS-SOP-29	Monitoring and measurement of product
30.	8.3	QMS-SOP-30	Control of nonconforming product
31.	8.4	QMS-SOP-31	Analysis of data
32.	8.5	QMS-SOP-32	Improvement
33.	8.5.1	QMS-SOP-33	Advisory notice
34.	8.5.1	QMS-SOP-34	Handling of customer Complaints
35.	8.5.1	QMS-SOP-35	Vigilance system
36.	8.5.2	QMS-SOP-36	Corrective action
37.	8.5.3	QMS-SOP-37	Preventive action