Quality Manual

Complies with
ISO 13485: 2016, EN ISO 13485:2016,
93/42/EEC – Medical Device Directive as amended by 2007/47/EC,
QSR 21 CFR 820,
Fifth Schedule of IMDR 2017 GSR 78 (E), KGMP requirements Requirements
REGULATION (EU) 2017/745 OF THE
EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017,
IS 23485:2019 Medical Devices — Quality
Management System Requirements and Essential Principles of
Safety and Performance for Medical Devices

BLUE NEEM MEDICAL DEVICES PRIVATE LIMITED

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Ramanagara Karnataka, 562112
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Scope of the QMS

Design and Development, Production, and Distribution of Sterile Non -Active Medical Devices for Urology, Gastroenterology, Radiology, Nephrology and Gynecology

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Company Profile

Blue Neem Medical Devices Pvt. Ltd, incorporated in 2008, has been focusing on creating and building a strong ecosystem of quality medical devices manufacturing. Our primary aim is to manufacture medical devices with World Class Quality at an affordable price.

Blue Neem has invested in a best-in-class infrastructure and our products are delivered by best-in-class work force. Our area of focus has been in the field of Urology, Gastroenterology, Radiology, Gynecology, Nephrology and Cardiology.

Blue Neem's world class manufacturing process is based on GMP and world class processes. With a team led by directors with strong complimentary skills, Blue Neem has seen a steady and robust growth since its inception.

With strong foundation of values that revolves around Customer Wellbeing, Integrity and Fairness, Execution Excellence and Continual Improvement, brand Blue Neem is well recognized in India and around the world for its quality, values and promise.

Blue Neem is headquartered in Harohalli and has its operations across India.

Blue Neem is operating from its highly sophisticated production unit with an operational area of 27,000 sq. ft. and the products are manufactured and assembled in class ISO 7 and in class ISO 8 environment. Quality control and packing are done in class ISO 7 clean rooms. The products are stored in a dust free clean environment.

QUALITY POLICY

Refer Annexure 9 for Blueneem Quality Policy

1.0 Purpose & Scope

1.1 Purpose of the document

This quality manual provides overall guidelines, structure and the purpose of quality management system deployed in Blue Neem Medical Devices Pvt ltd.

This Quality Manual overviews the Quality Management System and associated practices used by Blue Neem Medical Devices Pvt. Ltd. to ensure the Product Designed, Manufactured and Marketed by Blue Neem Medical Devices Pvt. Ltd. perform consistently, in accordance with the set objectives and applicable regulatory and quality standards.

The quality system complies with ISO 13485:2016 – Medical Devices – Quality Management Systems – Requirement for Regulatory Purposes and IS 23485: 2019 Medical Devices-Quality Management System Requirements and Essential Principles of Safety and Performance of Medical Devices. This manual also governs the creation of quality related documents. It will be revised, as necessary, to reflect the quality system currently in use.

1.2 Scope

The scope of the Quality Management System in Blue Neem Medical Devices Pvt ltd in Unit-1 and Unit-2 as fallows

Unit-1 Address: Plot Nos 270 & 271, Road No 5, Harohalli Industrial Area, II Phase, Kanakapura Taluk, Ramanagara Karnataka, 562112.
Scope: Design and Development, Production, and Distribution of Sterile Non -Active Medical Devices for Urology, Gastroenterology, Radiology, Nephrology and Gynecology.

Unit-2 Address: Plot No. 291, Road No. 2, Harohalli Industrial area Phase-2, Kanakapura Taluk, Ramanagara District, Karnataka 562112.
Scope: The provision of manufacturing services for Medical Tubing's and Medical Device components

1.3 Exclusions/non-applicability

Exclusions: Nil

Non-Applicable Clauses of ISO 13485:2016

#	Not Applicable Clauses	Justification for Non-applicability
1.	7.5.3 – Installation Activities	All medical devices under the scope are single use, sterile medical devices and hence installation is not required
2.	7.5.4 - Servicing Activities	All medical devices under the scope are single use, sterile medical devices and hence Servicing is not required

1.4 List of Applicable Standards

#	Standard	Description
		Harmonized Standards
1.	EN ISO 13485: 2016	Medical devices - Quality management systems - Requirements for regulatory purposes
2.	IS 23485: 2019	Medical Devices-Quality Management System Requirements and Essential Principles of Safety and Performance of Medical Devices
3.	EN ISO 14971:2019	Medical devices - Application of risk management to medical devices
4.	EN ISO 11607-1:2020	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
5.	EN ISO 11607-2:2020	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
6.	EN ISO 11737-1:2018/A1	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products.
7.	EN ISO 11737-2:2020	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
8.	EN ISO 11140-1:2014	Sterilization of health care products -- Chemical indicators -- Part 1: General requirements.
9.	EN 556-1:2001 /AC:2006	Sterilization of medical devices. Requirements for medical devices to be designated "STERILE". Requirements for terminally sterilized medical devices.
10.	EN ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements.
11.	ISO 11135:2014	Sterilization of health-care products -- Ethylene oxide -- Requirements for the development, validation and routine control of a sterilization process for medical devices
12.	ISO 11138-1:2017	Sterilization of health care products -- Biological indicators -- Part 1: General requirements
13.	GHTF/SG3/N99-10:2004 (Edition 2)	Quality Management Systems - Process Validation Guidance
14.	EN ISO 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
15.	EN ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer
16.	ASTM-F-1828-22	Standard specification for ureteral stents
17.	ASTM F1980-21	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
18.	ASTM D-4169-22	Standard Practice for Performance Testing of Shipping Containers and Systems
19.	ASTM F-640-20	Standard Test Methods for Determining Radiopacity for Medical Use
20.	EN ISO 11070:2014	Sterile single-use intravascular introducers, dilators and guidewires
21.	EN ISO 20697:2018	Sterile drainage catheters and accessory devices for single use
22.	ISO 10555-3: 2013	Intravascular Catheter – Sterile and Single-use Catheter Part 3: Central Venous Catheter
23.	ISO 9626:2016	Stainless steel needle tubing for the manufacture of medical devices — Requirements and test methods
24.	IEC 62366-1:2015/Amd 1:2020	Medical Devices Part 1: Application of usability engineering to medical devices: Amendment 1

25.	ISO 10993-1:2018	Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process
26.	ISO 10993-3:2014	Biological evaluation of medical devices Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
27.	ISO 10993-5:2009	Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity
28.	ISO 10993-6:2016	Biological evaluation of medical devices Part 6: Tests for local effects after implantation
29.	EN ISO 10993-10:2023	Biological evaluation of medical devices – Part 10: Tests for skin sensitization
30.	ISO 10993-11:2017	Biological evaluation of medical devices Part 11: Tests for systemic toxicity
31.	ISO 10993-17:2023	Biological evaluation of medical devices Part 17: Toxicological risk assessment of medical device constituents
32.	ISO 10993-18:2020	Biological evaluation of medical devices Part 18: Chemical characterization of medical device materials within a risk management process
33.	EN ISO 10993-23:2021	Biological evaluation of medical devices - Part 23: Tests for irritation
34.	ISO 14644-1:2015	Clean rooms and associated controlled environments Part 1 Classification of air cleanliness
35.	ISO 14644-2:2015	Cleanrooms and associated controlled environments -- Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration
36.	USP CHAPTER <85>	Bacterial endotoxins test USP Chapter <85>
37.	BS EN 13868:2002	Catheters, Test methods for kinking of single lumen catheters and medical tubing
38.	OECD 473 Guidelines	Test for Genotoxicity
Other Applicable Directives		
39.	EU Medical Device Directive 93/42/EEC	Council directive concerning medical devices
40.	MDCG 2021-24	Guidance on classification of medical devices
41.	MEDDEV 2.7/1 Rev. 4 June 2016	Clinical Evaluation: A Guide for Manufacturers and Notified Bodies Under Directives 93/42/EEC And 90/385/EEC
42.	MEDDEV 2.12-1 Rev 8 Jan 2013	Guidelines on A Medical Devices Vigilance System
43.	NB-MED 2.12-1 Rev 11	Post-Marketing Surveillance_(PMS)
44.	MDCG 2024-3	Guidance on content of the Clinical Investigation Plan for clinical investigations of medical devices
45.	MDCG 2020-7	Guidance on PMCF plan template
46.	MDCG 2020-8	Guidance on PMCF evaluation report template
47.	MDCG 2022-21	Guidance on Periodic Safety Update Report (PSUR) according to Regulation (EU) 2017/745
48.	MDCG 2020-6	Guidance on sufficient clinical evidence for legacy devices
49.	MDCG 2020-5	Guidance on clinical evaluation – Equivalence
Other Applicable Guidelines		
50.	QSR 21 CFR 820	Quality system regulation of US-FDA
51.	Fifth Schedule of IMDR 2017 GSR 78 (E) Requirements	Quality Management System for medical devices and in vitro diagnostic medical devices

Applicable Regulations		
52.	REGULATION (EU) 2017/745	REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017

2.0 Normative Reference

Blue Neem Medical Devices Pvt. Ltd. has used ISO 13485: 2016, EU 2017/745, 21 CFR Part 820, IS 23485:2019 and appropriate references as part of the preparation of all the documents related to the Quality Management System. The manual is divided into 8 sections corresponding to Quality System Requirements of the ISO 13485: 2016.

#	Standard / Reference	Description
1.	ISO 13485: 2016, EN ISO 13485: 2016	Medical Devices – Quality Management Systems – Requirements for regulatory purposes
2.	ISO 14971: 2019	Medical Devices – Application of Risk Management to Medical Devices
3.	93/42/EEC	Medical Device Directive, as amended concerning medical devices
4.	21 CFR Part 820	Quality System Regulations
5.	IMDR 2017	Medical Device Rules, 2017
6.	ISO 9000:2015	QMS fundamentals and vocabulary
7.	REGULATION (EU) 2017/745	REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017
8.	IS 23485:2019	Medical Devices — Quality Management System Requirements and Essential Principles of Safety and Performance for Medical Devices

3.0 Terms and Definition

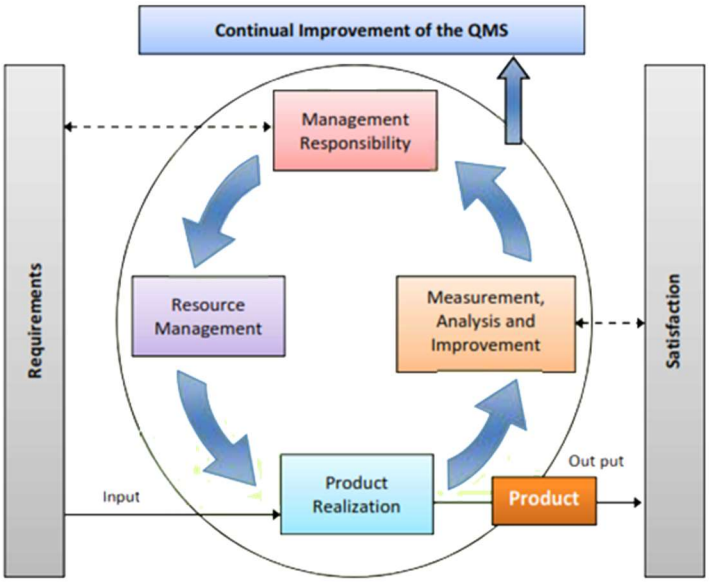
3.1 All definitions of terminologies used in this document are as per ISO 13485:2016 and other applicable standards, directives and guidelines.

3.2 Abbreviations: all abbreviations used in this manual are detailed in Annexure -11

4.0 Quality Management System

4.1 General Requirements

Blue Neem Medical Devices Pvt. Ltd. has established, documented, implemented, and maintains the effectiveness of its Quality Management System (QMS). We accomplish this mission in accordance with ISO 13485: 2016, EN ISO 13485: 2016, FDA's 21 CFR 820, IS 23485:2019 and our own internal management guidelines.



While implementing our Quality Management System Blue Neem Medical Devices Pvt. Ltd. Ltd. have:

- identified the processes needed for the Quality Management System and their application;
- determined the sequence and interaction of these processes;
- determined the criteria and methods required to ensure the effective operation and control of these processes;
- ensured the availability of information necessary to support the operation and monitoring of these processes;
- the process is monitored, measured, analyzed and whenever changes to the processes are required such changes are analyzed for its impact on the overall QMS, Regulatory and product risks and then implemented
- Implemented the actions necessary to achieve planned results and continually improve, and
- Maintain the effectiveness of our processes.
- A risk-based approach towards the processes is employed in order to mitigate all risks that are posed on the product by processes.
- a strategy for regulatory compliance, including compliance with conformity assessment procedures and procedures for management of modifications to the devices covered by the system.
- Considered all the requirements as specified in Article 10(9), section 2.4 of Chapter 1 of Annex IX and Section 6.4 of Annex XI of Regulation EU 2017/745.
  Reference documents: all Quality Procedures from QP-01 to 40, Individual Process/Functional SOP(s), Quality Objectives, Individual function(s) work instruction, specifically BNMD-RAD-WI-18 Regulatory Compliance Strategy Procedure, QP 29 Significant Change Notification,

The Roles undertaken by Blue Neem Medical Devices Pvt Ltd is depicted below:

Sl. No.	Product Category	Activity	Location
1	***Urology, Gastroenterology, Radiology, Nephrology and Gynecology***	Design and Development, Manufacturing, Packing, sterilization, Final Goods Storage and Distribution	Unit-1
2	***Not Applicable***	Incoming quality Inspection, Raw Material Storage, Extrusion and sub assembly	Unit-2

Unit-1 Address: Plot Nos 270 & 271, Road No 5, Harohalli Industrial Area, II Phase, Kanakapura Taluk, Ramanagara Karnataka, 562112.
Scope: Design and Development, Production, and Distribution of Sterile Non -Active Medical Devices for Urology, Gastroenterology, Radiology, Nephrology and Gynecology

Unit-2 Address: Plot No. 291, Road No. 2, Harohalli Industrial area Phase-2, Kanakapura Taluk, Ramanagara District, Karnataka 562112.
Scope: The provision of manufacturing services for Medical Tubing's, Medical Device components and sub assembly process.

All personnel who manage, perform, and verify work-affecting quality are responsible for implementing the quality system. The MR is responsible for coordinating, monitoring, and auditing the system. Implementation of the quality system is assessed regularly by way of Internal Audit (BNMD-QP-24), External Audit and Management Reviews (BNMD-QP-05).

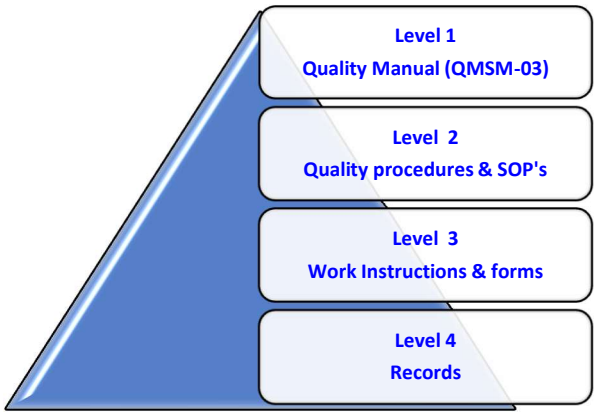
In our operations, subcontracting of work and outsourcing of processes are a necessity and proper controls have been established to ensure that the product or process conforms to the same specified requirements as those established within the QMS and its requirements. Outsourcing activities (BNMD-PUR-SOP-01) are identified, documented in the controlled data form, and the outsourced processes will be monitored for its conformity to the defined QMS processes.

Associated Procedure: BNMD-PUR-SOP-01 – Procedure for Purchasing

4.2 Documentation Requirements

4.2.1 General

This section describes the Quality Management System documentation adopted by Blueneem. The Quality Management System documentation has a four-tier structure as given below:



Level I	Consists of Quality Manual which includes Quality Policy, Quality Objective, expressing the overall intention and directions of Blue Neem Medical Devices Pvt. Ltd and provides overall guidance of the quality management system within the organization in line with ISO 13485:2016
Level II	The Quality Procedures provides the overall framework for each of the individual procedures including mandatory procedures to enable particular SOP's to be framed
Level III	Consists of Work Instructions for each of the activities under all procedures and SOP's and also Includes standard forms
Level IV	Consists of Records arising out of various operations

4.2.2 Quality Manual

Blue Neem has established and maintains a quality manual **(QMSM-03).** The quality manual includes the scope of the quality management system, documented procedures established for the quality management system, and describes the interaction between the processes of the Quality Management System.

4.2.3 Medical Device File/Technical Documentation

Medical Device File/Technical Documentation for all Medical Devices that are manufactured and supplied by Blue Neem Medical Devices Pvt. Ltd. Is established and maintained. The medical device file/ Technical Documentation reference the documents generated to demonstrate conformity to all the requirements of all appropriate standards and compliance with applicable regulatory requirements besides considering all the requirements of Article 10(4) and ANNEX II TECHNICAL DOCUMENTATION & ANNEX III TECHNICAL DOCUMENTATION ON POST-MARKET SURVEILLANCE of Regulation (EU) 2017/745. The contents of this documentation cover all the following information but not limited to:

a. General description and specifications of the medical device, intended use / purpose, and labelling, including any instructions for use,
b. Reference to previous or similar generations of the device.
c. Design and Manufacturing information
d. Specifications or procedures for manufacturing, packaging, storage, handling and distribution;
e. Procedures for measuring and monitoring;

f. General Safety and Performance requirements or Essential principles for Safety and Performance of Medical devices Checklist
g. Benefit-Risk analysis and Risk Management
h. Device verification and Validation
i. Declaration of Conformity as per Article 19 of Regulation (EU) 2017/745.
j. Post market Surveillance

Refer: Medical Device file [Technical files & Device Master File]
BNMD-RAD-WI-06 Post Market Surveillance, BNMD-RAD-SOP-01 Technical File Procedure.
BNMD-RND-SOP-02 Risk Management,
BNMD-RAD-WI-18 Regulatory Compliance Strategy Procedure

4.2.4 Control of Documents

Documents required by the quality management system shall be controlled.

The Documented procedures are defined and controlled. Whenever the documents undergo revision, they are reviewed and approved prior to use with adequate control of its revisions including revision history. When the regulatory and quality management system standards are revised the documents are updated accordingly, all documents are legible, identifiable and easily retrievable.

Obsolete documents are removed, and new (or updated) documents are issued by QMS Department in a controlled mechanism.

External documents are identified and their distribution is controlled. Technical documentation, EU declaration of Conformity, relevant certificates and amended and supplemented versions shall be available for the competent authorities for a period of at least 10 years after the last device covered by the EU declaration of conformity has been placed on the market. In the case of implantable devices, the period shall be at least 15 years after the last device has been placed on the market as per Article 10(8) of Regulation (EU) 2017/745.

Associated Procedure: BNMD-QP-01 Control of Documents

4.2.5 Control of Records

Records shall be established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system. Records shall remain legible, readily identifiable and retrievable.

Associated Procedure: BNMD-QP-02 Control of Records, BNMD-RAD-SOP-01 Technical File Procedure, BNMD-RAD-WI-10 Control Over labelling, IFU, BNMD-RAD-WI-11 Archiving, BNMD-RAD-WI-12 Applications and change notifications to NB & BNMD-RAD-WI-08 Registration with national competent authorities.

5.0 Management Responsibility

5.1 Management Commitment

The top management of Blue Neem Medical Devices Pvt. Ltd. is committed to the development, implementation and continual improvement of Quality Management System.
This goal is accomplished by:

a. Communicating within the organization the importance of meeting and exceeding customers, regulatory and legal requirements
b. Establishing quality policy and objectives and communicating these to all personnel in the organization
c. Conducting management reviews of the system
d. Ensuring the availability of resources
e. Top management has been periodically reviewing the Quality System to continue for the suitability.

Associated Procedure: BNMD-QP-03 Responsibility and Authority

5.2 Customer Focus

Top management commitment to customer focus is reflected on the documented quality policy and quality objectives, the management shall periodically communicate to the entire organization the importance of adherence and improvement of quality management system including the importance of meeting customer and regulatory requirements. The communication will be made through E-mail, newsletters, sessions, trainings, meetings, discussions and other modes of communication.

The products are designed to meet all customer requirements and shall be modified to meet the special requirements of specific customers.

Associated Procedure: BNMD-MRT-WI-02 Management Responsibilities

5.3 Quality Policy

Top Management has articulated the quality policy of the organization that is applicable to the role of the organization, its commitment to comply with requirements and maintain effectiveness of the quality management system. The quality policy provides the framework for establishing quality objectives. Quality policy is communicated to the entire organization through display, handouts and posters. The quality policy is reviewed periodically for its suitability during management review meetings.

Refer Annexure 9 of the Quality Manual

5.4 Planning

5.4.1 Quality Objectives

The quality objectives that are relevant to the applicable processes to meet the customer requirements, organizational requirements and applicable regulatory requirements. The quality

objectives are derived from the Quality Policy, which are measurable and are translated to relevant departmental procedures as measure of effectiveness.

Refer Annexure 8 of the Quality Manual

5.4.2 Quality Management System Planning

Quality management system processes are planned in order to achieve the quality objectives, each process shall identify its scope, process owner, supporting departments, measure of effectiveness, method of measurement, analysis, resource required and the procedure details. It is ensured that the changes to the QMS are gradual and do not affect the QMS which can have an adverse impact on the integrity of QMS.

The changes made to the processes shall be evaluated for their impact on the QMS, the impact on medical devices produced and controlled in accordance with ISO 13485:2016, IS 23485:2019 and other applicable standards and regulatory requirements. Risk based approach shall be taken for implement the changes.

Associated Procedure: BNMD-MRT-WI-02 Management Responsibilities, BNMD-QP-38 Change Control & QP 40 Quality Management System Planning

5.5 Responsibility, Authority, and Communication

5.5.1 Responsibility & Authority

The top management of Blue Neem Medical Devices Pvt. Ltd. has defined, documented and communicated the roles and responsibilities of personnel and interrelations within the organization to implement and maintain the Quality Management System. The roles and responsibilities of company personnel are detailed in (Annexure 2).

In addition to the overall interrelations of company personnel defined in Organization chart – Annexure 1, top management has identified those individuals who are competent and independent to serve as reviewers [Reporting Authority] for various functions. The detailed Job descriptions are provided in Annexure 2.

The management ensures that the employees of Blue Neem Medical Devices Pvt. Ltd. understand that quality is the responsibility of everyone. Blue Neem Medical Devices Pvt. Ltd. personnel have been given the authority and responsibility to enable them to assist in the achievement of quality objectives within their areas.
Reference document: QP 03 Responsibility and Authority

5.5.2 Management Representative

The top management, has appointed Management Representative as the head for this Quality Management System, and the Head QMS/RA as correspondent.

These Representatives has been given the responsibility and authority for:

a. Ensuring that the processes of the Quality Management System are established and maintained;
b. Reporting to top management on the performance of the Quality Management System on regular basis, to include the need for improvement(s);
c. Promoting the awareness of customer requirements throughout the organization.
d. Ensuring and promoting the awareness of regulatory requirements throughout the organization.

5.5.3 Internal Communication

The top management & functional heads and the QMS Executive ensure that appropriate communication processes are established within the organization, to include communication regarding the effectiveness of the Quality Management System.

Associated Procedure: BNMD-MRT-WI-02 Management Responsibilities

5.6 Management Review

5.6.1 General

The top management shall conduct management review meeting at a periodical interval of not more than six months to ensure continued suitability and effectiveness of the quality management system. The management representative shall spearhead the management review meeting in coordination with the top management and all process owners.

The review shall cover all required and applicable inputs in accordance with ISO 13485:2016 and other applicable regulatory standards. Decisions arising from the review are recorded, circulated and followed up for its effective implementation.

Associated Procedure: BNMD-QP-05 Management Review

6.0 Resource Management

6.1 Provision of Resources

Blue Neem Medical Devices Pvt. Ltd. ensures that resource requirements necessary to implement, maintain and continually improve the effectiveness of the Quality Management System are identified and provided.

Blue Neem Medical Devices Pvt. Ltd. also ensures that resources needed to meet regulatory and customer requirements and enhance customer satisfaction are identified and provided.

6.2 Human Resources

All personnel performing tasks that affect the product quality are ensured that they have requisite competence with respect to qualification, experience and skills. Whenever the gap is identified they are adequately trained before they are deployed on the task. such trainings are evaluated for their effectiveness.

Associated Procedure: BNMD-QP-06 Competence, Awareness & Training of Personnel

6.3 Infrastructure

Blue Neem Medical Devices Pvt. Ltd. providers and maintains the necessary infrastructure to achieve conformity to statutory, regulatory, and product requirements. Blue Neem Medical Devices Pvt. Ltd. has established and documented requirements for maintenance activities and their frequency.

Associated Procedure: BNMD-QP-07 Infrastructure

6.4 Work Environment

6.4.1 Work Environment

Blue Neem Medical Devices Pvt. Ltd. documented the requirements for work environment needed to achieve the conformity to product requirements. The following are considered in the creation of a suitable work environment.

a. Documented requirements for health, cleanliness and clothing of personnel if contact between such personnel and the product or work environment could affect the product performance.

b. Ensures that all the personnel, who are required to work temporarily under special environmental conditions within the work environment, are competent or supervised by a competent person.

6.4.2 Contamination Control

Blue Neem Medical Devices Pvt. Ltd. planned and documented the appropriate arrangements for the control of contaminated or potentially contaminated product in order to prevent contamination of the work environment, personnel or product.

Blue Neem manufactures sterile medical devices and towards this it ensures that the products are controlled for contamination with microorganisms and particulate matter and maintains the required cleanliness during assembly and packaging processes.

Associated Procedure: BNMD-QP-08 Work Environment and Contamination Control

7.0 Product Realization

7.1 Planning of Product Realization

At Blue Neem the product realization is planned taking into consideration the following

- The quality objectives of the organization
- The customer and regulatory requirements
- And the role of the organization

The planning includes customer product requirements and application, infrastructure, work environment, verification & validation methodology, product handling, storage, distribution methodology, Traceability and inspection & testing with acceptance criteria.

The planning ensures that the requirements of Article 10(1) of Regulation (EU) 2017/745 and thorough risk management process is employed throughout the product life cycle in accordance with EN ISO 14971:2019, Section (3) of General requirements of Chapter 1 of Annex I of Regulation (EU) 2017/745.

Associated Procedure: ***BNMD-MKG-WI-01 Product Need Document***
BNMD-RND-SOP-01 Research and Development
BNMD-RND-SOP-02 Risk Management

7.2 Customer Related Processes

7.2.1 Determination of Requirements Related to the Product

Blue Neem shall design and developed products either based on product requirements gathered from customers or develop a proof of concept of a product and take it to sample customers for the feedback on all aspects of the product. The information gathered include -

a. requirements specified by the customer, including the requirements for delivery and post-delivery activities
b. requirements not stated by the customer, but necessary for specified or intended use, as known like General Safety and Performance requirements as per Annex I of Regulation (EU) 2017/745 and Essential Principles of Safety and Performance of Medical devices as per Section II of IS 23485:2019 and section 6 of Chapter II of The MEDICAL DEVICES RULES, 2017.
c. applicable regulatory requirements related to the product, and
d. any user training needed to ensure specified performance and safe use of the medical device
e. any additional requirements determined by the organization
f. requirements of Article 10(1) of Regulation (EU) 2017/745
g. Essential principles of Safety and Performance of Medical Devices (refer Annexure-17)

Reference document: BNMD-RAD-L-09 General Safety and Performance Requirements
BNMD-RAD-WI-18 Regulatory Compliance Strategy Procedure

7.2.2 Review of Requirements Related to the Product

Blue Neem Medical Devices Pvt. Ltd. reviews documented product requirements prior to committing to a customer that a product can be supplied. During this evaluation, the company's sales representative ensures that product requirements are clearly defined, ambiguities are resolved, and that Blue Neem Medical Devices Pvt. Ltd. has the capability to meet the defined requirements.

In the event, a customer does not provide a documented statement of their requirements; the requirements are confirmed with the customer prior to the quotation being approved. When changes occur to requirements, Blue Neem Medical Devices Pvt. Ltd. will amend the associated documents and personnel affected by the change are notified.

7.2.3 Customer Communication

Blue Neem communicates with customers in relation to product information, enquiries, contracts, order handling, customer feedback, complaints, recall and advisory notices through a well-documented procedure of sales, marketing, feedback and regulatory.

Blue Neem maintains and provides technical documentation in its entirety or a summary thereof, upon requested by competent authority or regulatory authority.
Blue Neem Communicates with competent authorities, notified bodies, other economic operators, customers and/or other stakeholders in any context related to device and Quality Management System as per the following procedures as relevant:

Associated Procedures: BNMD-QP-22 Customer Complaints, BNMD-QP-21 Customer Feedback, BNMD-QP-23 Medical Device Vigilance System & BNMD-SLS-SOP-01 Sales Procedure, BNMD-RAD-WI-01 Reporting to Regulatory Authorities, BNMD-RAD-WI-16 Economic Operators, BNMD-RAD-WI-09 Control of EU Representative, BNMD-RAD-WI-12 Applications and change notifications to Notified body and BNMD-SLS-WI-02 Product Recall & Advisory Notice Procedure and QP 29 Significant Change Notification and QP 38 Change control.

7.3 Design & Development

7.3.1 General

Blue Neem designs and develops products that are determined from customer requirements from the market as well as devices that are innovatively new that will meet some of the needs that or hitherto unmet. The organization may outsource some of the design elements or process and such outsourced processes are controlled and monitored and meets all the requirements of Article 10(1) of Regulation (EU) 2017/745.
Reference document: BNMD-RND-SOP-01: RND Procedure

7.3.2 Design & Development Planning

A written plan to be established for every design and development process that defines each activity in stages, including design review, verification and validation points and methods appropriate for each stage, and that identifies the personnel responsible for each activity. The design process and its interface with other internal and external organizational groups will be defined as much as possible before the design process begins. Planning output will be updated as appropriate to be in line with the design progress.

At the concept, stage of product design and development the risk management of the product for entire product life cycle is carried out as per EN ISO 14971:2019.

7.3.3 Design and Development Inputs

The inputs relating to product requirements are determined and appropriate records are maintained. The inputs determined are:

a. Functional, performance, usability and safety requirements, according to the intended use;
b. Applicable regulatory requirements and standards;
c. Applicable outputs of risk management;
d. As appropriate, information derived from previous similar designs;
e. Other requirements essential for design and development of the product and processes in addition to Essential principles of Safety and Performance of Medical Devices (refer Annexure-17)

These inputs are reviewed for adequacy and approved. The input requirements should be complete, unambiguous, and able to be verified or validated, and not in conflict with each other.

7.3.4 Design and Development Outputs

The outputs from the design and development process are ensured to meet the design and development input requirements, provide appropriate information for purchasing, production provision, contain or make references to acceptance criteria and identify those characteristics of the design that are crucial to the safe and proper use and application of the product.

The final design outputs represent the result of the design process and consist of the final product, product specifications and drawings, purchase procedures, manufacturing work instructions and procedures that are used for production, sterilization and storage. The design and development outputs shall be in a form suitable for verification against the design and development inputs and outputs shall be approved prior to release. The records of design and development outputs are maintained in associated Design History File.

7.3.5 Design and Development Review

Design Reviews are conducted as per the design and development plan and it is ensured that the design results fulfil the requirements and identifies any issues that needs to be addressed. the reviews are conducted with the participation of all required and applicable personnel including specialists.

7.3.6 Design and Development Verification

Product designs are verified in accordance with planned arrangements as per the design plan against all the design inputs as per the design verification plan to ensure that all the design output meet the design input requirements. Whenever the intended use requires interface with other medical devices the verification is carried out when so connected with other medical devices.

7.3.7 Design and Development Validation

The design and development validations are performed in accordance with planned and documented arrangements to ensure that the final product meets the specified application or intended use.

The products that have substantial equivalence the clinical evaluation is carried out as per the applicable regulatory requirements and the products given for such clinical evaluation use is not considered to release into the market. For the product that do not have substantial equivalence clinical investigation is carried out as per regulatory requirements and clinical evaluation is done subsequently to meet regulatory requirements. Clinical investigation shall be followed as per the requirements said in the Article 61 of Chapter VI of Regulation (EU) of 2017/745.

Reference Document: BNMD-RAD-WI-05 Clinical Evaluation

7.3.8 Design and Development Transfer

Blue Neem Medical Devices Pvt. Ltd. documented the procedures for design transfer of design and development output to manufacturing. The procedures ensure that the design and development outputs are verified as suitable for manufacturing before becoming final production specifications and that production capability can meet product requirements.

7.3.9 Control of Design and Development Changes

Whenever a design change is required after the design transfer to manufacture is completed and the product is in production, the change is evaluated as per engineering change order process developed internally and then implemented following the entire design and development process as defined in this manual. If design change or process change is recommended because of change or revision of common specifications as specified in article 9 and Article 10 (9) 1st paragraph based on risk class.

Whenever such design change is called for after the product has been awarded regulatory approvals such changes that qualify as significant change are notified to regulatory authorities.

Reference document: **BNMD-QP-11 Engineering Change Procedure**

7.3.10 Design and Development Files

Blue Neem Medical Devices Pvt. Ltd. maintains a design history file for each medical device type or medical device family. This file includes, or referenced all documents from concept to design transfer including design changes after the design transfer. This file is maintained as per control of documents for specified period.

Change control to keep series production in conformity related to design, characteristics applied harmonized standards, state of the art taken into account in timely manner (MDR Art. 120(3) - No significant changes in the design and intended purpose. Qualification of a change as "significant" according to MDR Art. 120 (3) shall be determined on a case-by-case basis (see MDCG 2020-3). However, - limitations of the intended purpose - design changes related to corrective actions assessed

and accepted by the Competent Authority are not considered "significant" in the sense of Art. 120(3) MDR.

Associated Procedure: Refer: BNMD-RND-SOP-01 Research and Development Procedure, BNMD-RND-WI-04 State of the Art, BNMD-RAD-WI-07 Product Classification, BNMD-RAD-WI-13 Issue of declaration of conformity & BNMD-RND-WI-02 PMCF, QP 29 Significant Change Notification & BNMD-RAD-WI-06 Post Market Surveillance.

7.4 Purchasing

7.4.1 Purchasing Process

Purchasing of materials and parts are done from suppliers after the suppliers have been evaluated to meet the defined evaluation criteria applicable for each category of materials and parts. The evaluation criteria for selection of suppliers is determined with the risk-based approach taking the effect of the purchased product on the product realization process and final product.

The purchasing activities include material planning, purchasing of raw materials, consumables, spares and sub-contracting of production processes.

7.4.2 Purchasing Information

All purchase orders include a clear and complete description of the material being purchased, including all applicable requirements for quality system, manufacturing, inspection, testing and acceptance criteria. Purchasing documentation along with engineering documents where applicable are reviewed to ensure that pertinent quality requirements are clearly stipulated, and approved suppliers have been selected.

7.4.3 Verification of Purchased Product

It is the objective of Blue Neem Medical Devices Pvt. Ltd to ensure that the purchased products meet the specified purchasing requirement and to minimize defects and errors. The purchased products are verified as per defined Quality Plan.

a. Purchase products are verified on receipt before taking to stock or issued to production. The verification includes inspection, testing, verification as applicable to ensure that the purchased products meet the specified purchasing requirements.
b. The verification methods are carried out in line with established international standards based on the performance of the suppliers and proportionate to the risks associated with the product.

Associated Procedure: BNMD-QP-13 Purchasing, BNMD-QP-14 Verification of purchased product, BNMD-PUR-SOP-01 Purchasing Procedure & BNMD-IQC-SOP-01 Incoming Quality Control Procedure.

7.5 Production

7.5.1 Control of Production

At Blue Neem the production is planned, controlled, monitored and carried out in accordance with product requirements and process specifications including

- the requirements of the device
- suitable equipment
- monitoring and measuring devices
- qualification of infrastructure
- competence of personnel

The products under Blue Neem are manufactured under batch production method and suitable traceability and identification of batches are established.

Blue Neem maintains job cards for each product batch or order that provides traceability to the extent needed and identifies the amount manufactured, and amount that is approved for distribution which meets the requirements of Article 10(1) of Regulation (EU) 2017/745.

Associated Procedure: BNMD-QP-15 Production, BNMD-RAD-WI-10 Control over labelling, IFU & Product information.

7.5.2 Cleanliness of Product

a. At Blue Neem, we have established clean room manufacturing process as per regulatory requirements, all materials and products that enter the clean room are ensured they are clean.
b. All products are ensured that they are clean before sterilization.
c. It is ensured that no process agents are formed during the manufacturing process of products.

Associated Procedure: BNMD-PRD-SOP-01 Production Procedure & BNMD-PRD-WI-01 Material handling to prevent contamination

7.5.3 Installation Activities

NOT APPLICABLE- since no product installation and verification activities are involved either by the organization or by authorized agents.

7.5.4 Servicing Activities

NOT APPLICABLE- since servicing is not a specified requirement

7.5.5 Particular Requirements for Sterile Medical Devices

Blue Neem has established the process for sterilization of each batch of products and maintains the records of the process parameters of sterilization for each batch.

The organization has validated the sterilization process according to ISO 11135 standards

Associated Procedure: BNMD-PRD-WI-02 – Sterilization out Source & BNMD-PRD-WI-39 Sterilization In-house

7.5.6 Validation of Processes for Production

Each batch of the products manufactured at Blue Neem are verified based on acceptance criteria defined for the finished product. There are no processes involved in the production that required verification after delivery to customer or during use of the product.

The process validations are carried out with appropriate defined criteria for acceptance, equipment qualification, qualification of personnel, appropriate statistical techniques with rationale for sample size and special methods if any. The processes are re-validated periodically.

Computer software that are used in product realization and particularly production are validated as per defined criteria in accordance with risk-based approach.

Associated Procedure: BNMD-PRD-WI-03 Identification of Special Processes & BNMD-PRD-WI-04 Validation of Special Processes

7.5.7 Particular Requirements for validation of process for Sterilization and sterile barrier systems

The organization has validated the sterilization process according to ISO 11135 standards

Refer – Sterilization validation reports

Associated Procedure: BNMD-PRD-WI-02 – Sterilization out Source, BNMD-PRD-WI-39 Sterilization In-house & BNMD-PRD-WI-05 Out-source Sterilization Process validation

7.5.8 Identification

The identification system used by Blue Neem Medical Devices Pvt. Ltd. ensures that Raw materials, finished product and manufacturing material are properly identified throughout the entire process from receiving of purchase material to delivery of finished product. The finished products are identified through batch numbering system throughout the lifecycle and Unique Device Identification System is in place satisfying the requirements of Article 27 of Regulation (EU) 2017/745.

The returned products are identified separately and then segregated to distinguish from conformed products.

Associated Procedure: BNMD-QP-17 Identification & Traceability
BNMD-RAD-WI-19 Unique Device Identification-UDI-Management

7.5.9 Product Traceability

7.5.9.1 General

The backward traceability of components and materials of each batch of the products are maintained in accordance with risk associated with the component or material as per regulatory requirements. The traceability requirements of the components or materials purchased from the suppliers are communicated to them and ensured that they adhere to such requirements.

The forward traceability is maintained through batch numbering system, supplied to our first level of customers and they are advised to maintain the second level of traceability of products.

7.5.9.2 Requirements for Implantable Medical Devices

The traceability requirements for implantable medical devices manufactured by Blue Neem are maintained for a period of 15 Years, with specific information related to components, materials, conditions of work environment and quality control and quality assurance reports.

The distributors who are our customers are advised to maintain the records of distribution of the implantable medical devices with traceability for a period of 15 years and the same is incorporated into the agreement entered upon with them.

Associated Procedure: BNMD-QP-17 Identification & Traceability

7.5.10 Customer Property

The customer properties that are received by Blue Neem are of sample product in nature and they are safe guarded against loss, damage and unsuitability for use until as agreed upon with the customer.

If the customer property is lost or damaged or unsuitable for use the same will be reported to the customer.

Blue Neem does not collect any data or health information from the patients through it's products

Associated Procedure: BNMD-MRT-WI- 01 Customer property

7.5.11 Preservation of Product

Blue Neem shall preserve the products in conformity to the product requirements during the entire product realization processes particularly during production, sterilization, packaging, storage and distribution. The preservation includes protection from alteration, contamination or damage when exposed to undesirable conditions including hazardous conditions.

Associated Procedure: BNMD-QP-19 Preservation of Product

7.6 Control of Monitoring & Measuring Devices

7.6.1 Blue Neem Medical Devices Pvt. Ltd. has identified the measuring and monitoring devices and the associated applications needed to provide evidence of conformity to product requirements. A documented procedure has been established to ensure that monitoring/measurement can be carried out and is consistent with the product and regulatory requirements.

7.6.2 Blueneem has established a procedure for control for periodic calibration measuring and monitoring devices used to determine product conformance to applicable specifications. The level of confidence in the control and calibration system are established as such as to provide confidence in decisions or actions based on measurement data.

7.6.3 Measuring and monitoring devices are calibrated in accordance with requirements and certified to standards traceable to the NABL. Measuring and monitoring devices are used in such manner that the measuring uncertainty is known and is consistent with the required accuracy.

7.6.4 Measuring and monitoring devices are calibrated at periodic intervals established on the basis of stability, purpose, and degree of usage of the equipment.

7.6.5 All instruments are labeled with calibration sticker denoting date of calibration, due date of next calibration.

7.6.6 When equipment is found to be out of tolerance, the validity of previous testing or inspection are assessed and any remedial actions that may be necessary are determined. Production items which may be non-conforming due to the faulty test equipment are identified and segregated until investigation can identify their proper status.

7.6.7 Calibration records are maintained by Quality Assurance Department on all inspection, measuring and monitoring devices.

7.6.8 If any outsourcing processes, Equipment calibration are done as per the calibration plan.

Associated Procedure: ***BNMD-QP-20 Control of Monitoring and Measuring equipment & BNMD-QAD-WI-01– Calibration of Devices***

8.0 Measurement, Analysis & Improvement

8.1 General

Blue Neem has planned and implemented the Monitoring, Measurement, Analysis and Improvement Processes needed to demonstrate conformity of the product, to improve the effectiveness of the quality management system. This includes determination of applicable methods, including statistical techniques, and the extent of their use.

8.2 Monitoring and Measurement

8.2.1 Feedback

Feedback is obtained systematically and periodically from customers, production and post-production stages on various aspects including meeting customer requirements, regulatory requirements and market requirements. The customer feedback is obtained periodically on the performance and clinical effectiveness of the product and also when modification of the product is carried out.
Feedback is analyzed to calculate customer satisfaction indices and reviewed in management review meetings.

The feedback collected from post production activity will serve the requirements of Part-A and Part-B of Annex XIV and Article 83, 84, 85, 86 of Section (1) of Chapter VII of Regulation (EU) 2017/745.

Associated Procedure: BNMD-QP-21 Customer feedback
BNMD-RAD-WI-05 Clinical Evaluation, BNMD-RND-WI-02 Post-market Clinical Follow-up, BNMD-RAD-WI-06 Post Market Surveillance

8.2.2 Complaint Handling

Customer complaints are handled in accordance with the complaint handling procedures as per applicable regulatory requirements. The procedure includes

a. Receiving and recording information,
b. Evaluating information to determine if the feedback constitutes a complaint,
c. Investigating complaints,
d. Determining the need to report the information to the appropriate regulatory authorities,
e. Handling of complaint-related product,
f. Determining the need to initiate corrections or corrective actions.

If any complaint is not investigated, justification shall be addressed as relevant.

Associated Procedure: BNMD-QP-22 Customer Complaint

8.2.3 Reporting to regulatory authorities

Separate procedures are established and followed as per applicable regulatory requirements related to adverse events, reporting of serious incidents, device recall, field safety corrective action and advisory notices

Associated Procedure: BNMD-QP-23 Medical Device Vigilance System & BNMD-SLS-WI-02 Product Recall & Advisory Notice Procedure, BNMD-RAD-WI-01 Reporting to Regulatory Authorities, BNMD-RAD-WI-16 Economic Operators, BNMD-RAD-WI-12 Applications and change notifications to Notified body, Annexure -4 MEDICAL DEVICE ADVERSE EVENT REPORTING FORM, Annexure -3 for Field Safety Notice, Annexure -2 for Manufacturer's Field Safety Corrective Action Report.

8.2.4 Internal Audit

Blue Neem Medical Devices Pvt. Ltd. has established a procedure and conducts internal audits as minimum once in four months to determine if the quality management system conforms to the planned arrangements, to the applicable regulatory requirements and if any other applicable regulatory requirements established by the company, and is effectively implemented and maintained.

Key personnel are identified and trained as per ISO 19011 for internal audits, an audit program has been designed and implemented and identifies an audit schedule based on the importance of the areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency, methods, responsibilities and requirements for planning and conducting audits, and for reporting and maintaining results, are defined and documented in the Internal Auditing Procedure BNMD-QP-24.

The management responsible for the area being audited is responsible for ensuring that actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities include the verification of the actions taken and the reporting of verification results.

Associated Procedure: BNMD-QP-24 Internal Audit

8.2.5 Monitoring & Measurement of Processes

All processes are measured for the effectiveness of the quality management system of that process through measurable data defined as measure of effectiveness. Whenever the measure of effectiveness is not achieved correction and corrective actions are taken as appropriate.

8.2.6 Monitoring & Measurement of Product

Monitoring and measurement of materials or products are carried out at the incoming stage of materials, in process of production and finished goods inspection.
The acceptance criteria, identification of personnel authorizing the product, the test equipment used and the identification of personnel performing inspection and testing for implantable medical devices are recorded and maintained as per regulatory requirements.

8.3 Control of Nonconforming product

8.3.1 General

Products which do not conform to the defined quality requirements are identified and controlled to prevent its unintended use or delivery. The controls and related responsibilities and authorities for dealing with nonconforming product are defined. The evaluation of nonconformity includes a determination of the need for an investigation and notification if any to external party responsible for the nonconformity. The records of the nature of nonconformities and any subsequent action taken, including the evaluation, any investigation and the rationale for decisions are maintained.

8.3.2 Action in response to nonconforming product detected before delivery

Blue Neem takes appropriate measures to eliminate the detected non-conformity and ensures that nonconforming product is accepted by concession only and justification is provided, approval obtained, and applicable regulatory requirements are met for such acceptance. Records for the same are maintained. The acceptance is given only for non-conformities that does not alter or affect the intended use or application of the product.

8.3.3 Action in response to nonconforming product detected after delivery

When nonconformance product is detected after delivery or use has started Blue Neem Ltd. take action appropriate to the effects, or potential effects, of the nonconformity, by issuance of advisory notice or product recall as per regulatory requirements.

Associated Procedure: QP 25 Control of Non-Conforming Product

8.3.4 Rework

The product rework is performed when a non-conforming product is identified and it is ensured that the rework does not adversely affect the product, such reworked product is verified to ensure that admits the applicable acceptance criteria and regulatory requirements. The procedure of inspection of reworked product is same as the original procedure of inspection of products.
Associated Procedure: BNMD-PRD-WI-47 Rework process

8.4 Analysis of Data

a. Blue Neem Collects and Analyses appropriate data to demonstrate the suitability and effectiveness of the Quality Management System and to evaluate where improvement of the Quality Management System can be made.

b. The analysis of data provides information relating to customer satisfaction, conformity to product requirement, characteristics and trends of processes and products including opportunities for preventive action and suppliers.

c. The sources of data for analysis include the following:
   1. Feedback from Customers, Production and Post Production
   2. Customer complaints
   3. Conformity to product requirements from Sales, Customer Support, DND, Production and post-production activities
   4. Characteristics and trends of processes from each of the Functions as per the measurement of quality of respective processes
   5. Characteristics and trends of products in the market
   6. Suppliers
   7. Internal audits and external audits
   8. Customer support reports

Associated Procedure: BNMD-QP-26 Analysis of Data

8.5 Improvement

8.5.1 General

Blue Neem improves the effectiveness of the quality management system using the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

8.5.2 Corrective Action

Blue Neem acts to eliminate the root cause of nonconformities to prevent recurrence by taking corrective actions taken are appropriate to the effects of the nonconformities encountered. The corrective action includes

- Reviewing nonconformities (including customer complaints)
- Determining the causes of nonconformities,
- Evaluating the need for action to ensure that nonconformities do not recur,
- Determining and implementing action needed,
- Records of the results of action taken,
- Reviewing corrective action taken.

Associated Procedure: BNMD-QP-27 Corrective action and Preventive Action

8.5.3 Preventive Action

Blue Neem determines action to eliminate the root cause of potential nonconformities to prevent their occurrence. The preventive action includes:

- Determining potential nonconformities and their causes
- Evaluating the need for action to prevent occurrence of nonconformities
- Determining and implementing action needed
- Records of results of action taken
- Reviewing preventive action taken

Associated Procedure: BNMD-QP-27 Corrective action and Preventive Action

Revision History

Amendment / revision		Description	Insert Page / Rev	Remove Page / Rev
No.	**Date**			
R1	10-Oct-2018	Site Specific Quality Management System for Harohalli Head Quarters	NA	NA
R2	26-Mar-2020	Scope of the QMS changed with reference to the recommendation from Certification Body	1 of 33	NA
R3	02-Jun-2020	Scope of the QMS changed with reference to the additional products added under certification scope	1 of 33	NA
R4	20-May-2021	Scope of the QMS changed mentioning only ranges of products	1 of 33	NA
R5	12-May-2022	REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 added as applicable regulatory requirement	1, 10, 11 of 33	NA
R6	08-Jun-2023	List of Applicable Standard is updated	9, 10 of 33	NA
R7	05-Dec-2023	1.2 scope is updated for unit-2 and 4.1 general requirements are added for unit-1 and Unit-2	8, 14 of 33	NA
R8	10-Jul-2024	a) Requirements of Regulation (EU) 2017/745 in all applicable sections, clauses and sub clauses are incorporated and procedural reference is updated b) 1.1 Purpose is updated with IS 23485:2019 requirements c) 1.4 List of applicable standards is updated with IS 23485:2019 requirements d) Overall compliance of Quality Manual with IS 23485:2019 requirements is updated e) 7.2.1 Determination of Requirements related to product: requirements related to Essential Principles of Safety and Performance of Medical devices is incorporated and addressed to comply with the same as applicability in 7.3.3.	01 to 34	NA