SECTION 1: SIGNATURE PAGE

APPROVALS:
(Approvals are electronically recorded in the eQMS.)

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Corporate VP of Operation and Quality & Regulatory Affairs: Jeff Root

DOCUMENT CHANGE RECORD:

Rev.	Date	Description of Change
09	05/16/19	Updated Jeff Root's title to reflect current management duty. Added ISO13485 Medical devices -Quality management systems -Requirements for regulatory purposes in Section 4/5/6/7/8 Reference Documents
08	05/14/19	Updated exclusions to remove 6.4.1.a, 7.2.1.d, 7.2.2.d, 7.5.2, 7.5.6, 8.2.1, 8.5.1, 8.5.2.e, 8.5.3.e. Added exclusions 4.2.3a, 4.2.3.b, 4.2.3.e, 4.2.3.f, removed "Elite Plastics", updated approval names to reflect current management.
07	05/03/18	Update 6.4.2, 8.5.1, 8.5.2.e, 8.5.3.e to clarify non-applicable clauses.
06	04/13/18	Update to comply with 13485:2016 changes/requirements.
05	04/13/18	This revision number was intentionally skipped.
04	11/04/16	Update process flow chart to reflect GMN Core Process and SIPOC. Clarify GMN requirements related to advisory notices and adverse events reporting in 8.5.1.
03	11/16/15	Clarification of applicability and additions to scope as it pertains to specific division sites. Change format to align with 00-QM-01.
02	02/11/15	Change QM number to 00-QM-MED to show as a GM Nameplate Corporate Manual that applies to all divisions that certify to the ISO 13485 standard.
01	10/15/13	2587-Change QM number to 01-QM-MED, clarify distinction between the 2 quality manuals, update exclusions to include 7.3.7, other minor clarifications.
00	05/28/13	NEW-Creation of Quality Manual

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SECTION 2: QUALITY POLICY

The quality policy of GM Nameplate is to provide products that meet or exceed customer expectations, comply with all applicable regulations, continually improve in everything we do, and maintain the effectiveness of the quality management system.

What our quality policy means to us:

We provide products that meet or exceed customer expectations by using the ISO 9000 family of standards as our benchmarks. We employ proven quality management principles within the framework of our quality management system to enhance customer satisfaction and continually improve our performance and capabilities.

We comply with all regulations by using our quality management system as a tool to promote ethical compliance to applicable statutes, regulations, and industry standard requirements.

We continually improve in everything we do through our commitment **to maintaining the effectiveness of our quality management system.**

SECTION 3: INTRODUCTION

3.1 General

GM Nameplate is a global manufacturer that provides custom-engineered solutions to leading medical device companies worldwide. GM Nameplate capabilities include user interface devices, front panel integration, labels, nameplates, safety decals, plastic molding and decorating, quick-turn prototyping, die-cut components, value-added assemblies and more.

GM Nameplate offers contract manufacturing services for touch screens, membrane switches and other switch technologies, biosensors, value-added assemblies to its medical device clients. These products are considered components and are not a finished medical device. GM Nameplate does not manufacture any finished medical device product per medical device description.

GM Nameplate's Quality Management System (QMS) described by this Quality Manual covers the manufacturing of various components for medical device products at all divisions of GM Nameplate that are certified to ISO 13485.

While GM Nameplate uses a corporately driven QMS, each manufacturing site can differ in their processes. Site specific documentation "level 3 procedures or (work instructions)" further defines the requirements of the QMS for the respective manufacturing sites.

3.2 Scope

Our policies provide a framework to ensure the conformity and effectiveness of GM Nameplate's QMS to ISO 13485 requirements based on the product mix of each specific division. The scope statement for each division is such:

a) Washington Division: Manufacture of graphic and functional components for medical device industry.

b) Oregon Division: The manufacture and value-added assembly of graphic, functional, electronic, and user interface technology products for aerospace, automotive, medical, computer, industrial and other industries.

The requirements of this manual are communicated to all of GM Nameplate's employees in full or in part, depending on scope of employee's responsibilities and impact on the quality system and/or product integrity.

3.3 Application

Products are custom user interface devices, front panel integration, labels, nameplates, safety decals, and decorating, quick-turn prototyping, die-cut components, and assembly of medical device components, for medical device and In-Vitro diagnostic industries.

GMN is a contract manufacturer of non-sterile, non-implantable medical device components. GMN does not sell or distribute finished medical devices to end users. All medical device components are shipped to the medical device customer for further processing. Further GMN does not install nor provide any furthering services beyond addressing normal workmanship warranty claims.

Therefore, the following clauses of ISO 13485 are excluded from GM Nameplate's QMS for medical devices:

a) 4.2.3 Medical device file sub-clauses a, b, e, f

Exclusion justification: GM Nameplate is a contract manufacturer and does not design and/or develop medical device products.

b) 7.3 "Design and development" and all sub-clauses.

Exclusion justification: GM Nameplate is a contract manufacturer and does not design and/or develop medical device products and therefore does not know the general description of the medical device, intended use/purpose, and labelling, including any instructions for use, product specifications, installation requirements or servicing procedures.

Additionally, the following clauses of ISO 13485 are considered non-applicable to the QMS for medical devices:

c) 6.4.2) Contamination control: "For sterile medical devices, the organization shall document requirements for control of contamination with microorganisms or particulate matter and maintain the required cleanliness during assembly or packaging processes"

Non-applicable justification: GMN does not have any particular customer requirements for contamination control.

d) 7.5.3) “Installation Activities”

Non-applicable justification: GMN does not install products.

e) 7.5.4) “Servicing activities”

Non-applicable justification: GMN does not service products.

f) 7.5.5) “Particular requirements for sterile medical devices”

Non-applicable justification: GMN does not manufacture, assemble or distribute sterile medical devices.

g) 7.5.7) “Particular requirements for validation of processes for sterilization and sterile barrier systems”

Non-applicable justification: GMN does not manufacture, assemble or distribute sterile medical devices.

h) 7.5.9.2) “Particular requirements for implantable medical devices”

Non-applicable justification: GMN does not manufacture, assemble or distribute implantable medical devices.

SECTION 4: QUALITY MANAGEMENT SYSTEM

4.1 General Requirements

GM Nameplate has identified and established a documented quality management system (QMS) and applied processes throughout the organization to maintain the effectiveness of the QMS.

4.1.1 GM Nameplate is registered with the Food and Drug Administration (FDA) as a contract manufacturer.

4.1.2 The following processes are needed for the QMS based upon GM Nameplate’s role as a registered contract manufacturer. These processes apply to the manufacture of products identified in the scope of this manual, section 3.2.

a) Quoting

b) Order Processing

c) Advanced Product Quality Planning (APQP)

d) Manufacturing

e) Inspection and Packaging

f) Product Audit and Ship

g) Dispositioning Nonconforming Product

h) Document Control

i) Purchasing

j) Calibration

k) Training

l) Hiring

m) Receiving Inspection

n) Internal Audits

o) Management Review and Planning

The sequence and interaction of these processes is depicted at Figure 1 on the following page.

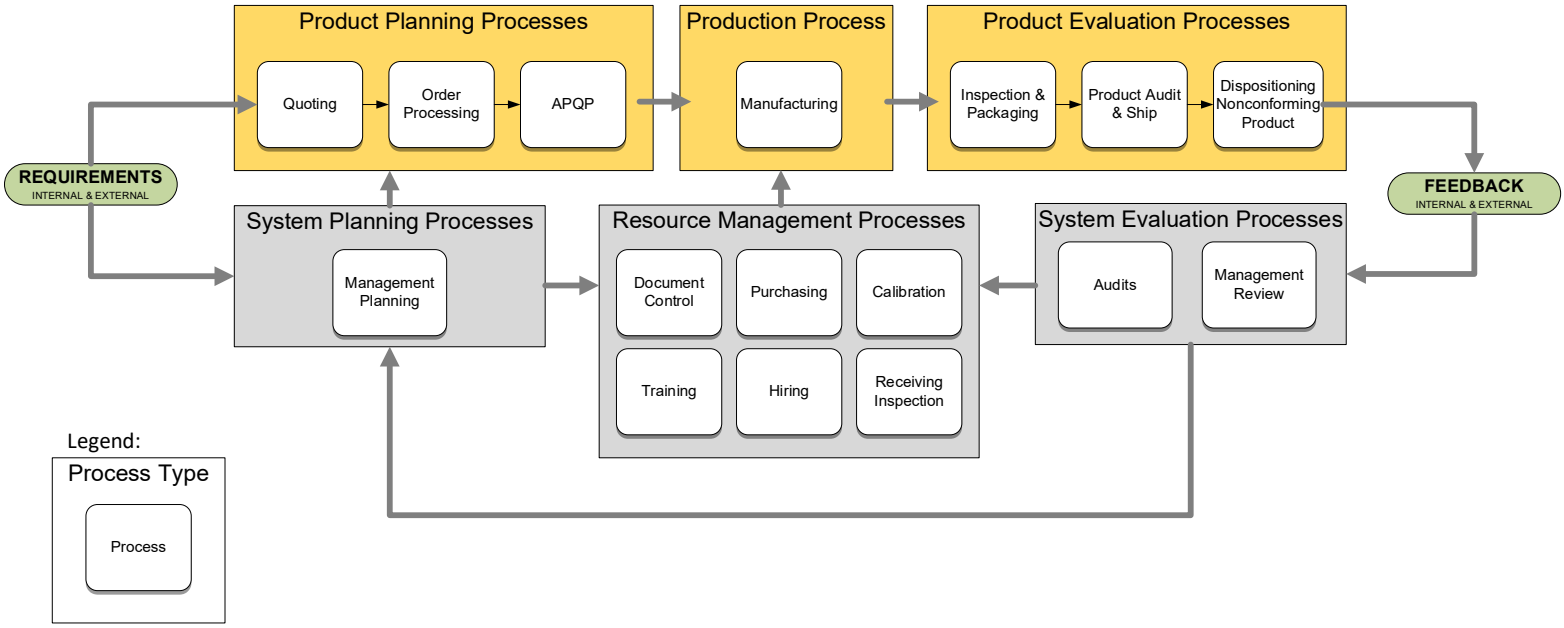


Figure 1 – QMS Process Flow Chart

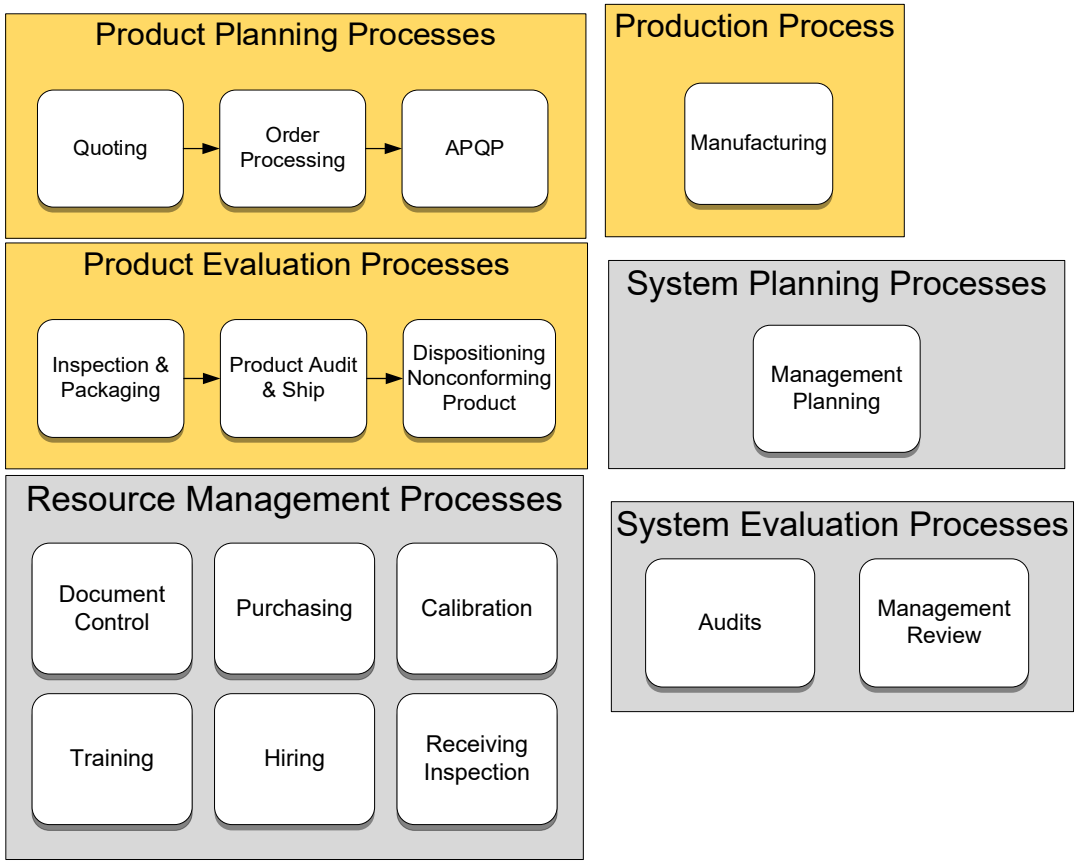


Figure 2 -Expanded view of QMS processes

4.1.3 The control and support of these processes are assured by:

a) Determination of the sequences and interactions of these processes,

b) Determination of the criteria and methods, including risks to ensure operation and control of the process are effective,

c) Identification and availability of resources and information,

d) Defined monitoring, measuring and analysis,

e) Implementation of actions necessary to achieve the planned results and to maintain the effectiveness of these processes, and

f) Implementation of the controls for outsourced processes that affect product quality.

4.1.4 Changes to quality management system processes are controlled through Management Planning and Review. These controls include:

a) An evaluation of the impact of proposed changes upon the QMS,

b) An evaluation of the impact of the proposed changes upon products produced under the QMS and intended for incorporation into medical devices, and

c) Review and approval of proposed changes in accordance with applicable regulatory requirements.

4.1.5 Outsource processes are monitored and controlled. Controls are:

a) Proportionate to the risks associated with the ability of the supplier to provide the outsourced process, and

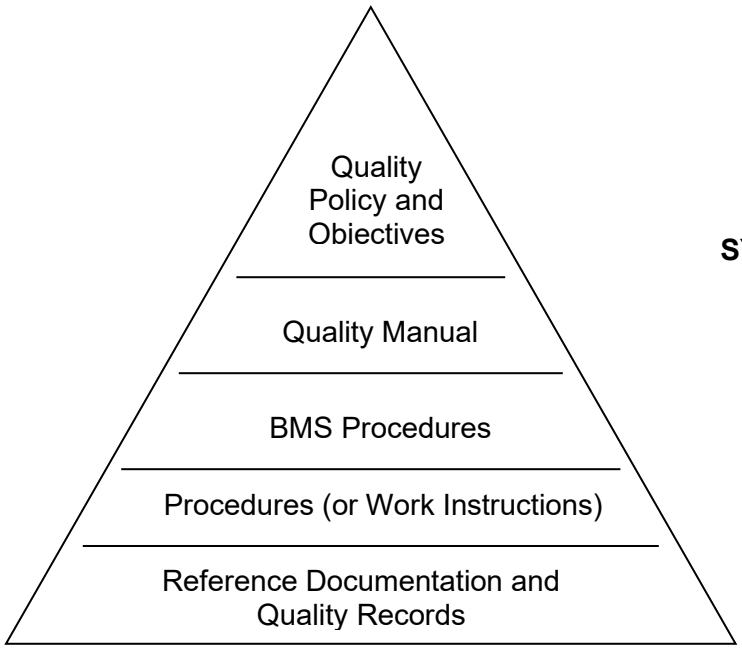
b) Include receipt of a signed Supplier Quality Agreement, 00-GMNSQA.

4.1.6 Software used in the application of the QMS is validated prior to use and after any changes to the software, as appropriate. Documented procedures define the requirements for software validation, including the activities needed. The extent of their application is based upon the risks associated with the software application. Records of software validation are maintained per 00-QA-105, Record Control.

4.2 Documentation

4.2.1 General

GM Nameplate has established a comprehensive QMS for the purpose of assuring the achievement of its quality policy and objectives. Documents are approved electronically using an eQMS system.



QUALITY MANAGEMENT SYSTEM DOCUMENTATION

Requirements for documentation may originate internally, from the customer, or as they might be required by ISO 13485 and/or FDA regulations.

Management ensures that employees have access and awareness of procedures related to their job responsibilities by providing access to controlled document via computer or binder of controlled paper copies of procedures and required forms.

4.2.2 Quality Manual

GM Nameplate has established and maintains a quality manual to define the scope of the QMS requirements and to provide justifications for any exclusion of the ISO 13485 standard.

This Quality manual provides reference to the procedures established for the QMS and also shows the relationship between the procedures and the requirements of the quality management standards.

GM Nameplate's document structure and document definitions are as such:

The **Quality Policy** is a statement of our commitment to our customers and is a driving force of our QMS.

Quality Objectives are statements of measurable goals to support our quality policy.

Level 1: The **Quality Manual (QM)** is a brief, clear description of the QMS requirements. As a corporate document, the quality manual conveys the quality policy to the specified divisions. The manual provides reference to the procedures established for the QMS**.** The quality manual shows the relationship between the procedures and the requirements of the quality management standards.

Level 2: BMS Procedures are corporate documents used to define in further detail the principles and strategies used to support the elements of the QMS. BMS Procedures are used for groups of people allowing a clear definition of responsibility, interfaces, and the specified way to perform an activity or activities.

Level 3: Procedures (or Work Instructions) are the documents that provide a specified way to perform an activity or several related activities. Procedures may take the form of work instructions. These documents may be created and maintained by a single division or by GM Nameplate Corporate They define what tasks are involved, how they are to be performed, and what reference documentation is needed to perform the task.

Level 4: Reference Documentation is the documentation that needs to be consulted in order to follow a procedure or work instruction. The most common reference documentation used at GM Nameplate is the work order ticket (job ticket) which contains the specific requirements for each order, including the part number, materials, specifications, drawings, schedule, stations sequences, ship date and method, etc.

Level 4: Records show evidence of meeting quality requirements, and retain as necessary to ensure effective planning, operation and control of QMS processes.

Quality System Requirements Imposed by Regulatory Authorities are documented at divisional level QMS documentation as applicable to industries and customers served.

GM Nameplate personnel have access to QMS documentation and are made aware of procedures including changes and revisions needed to carry out their responsibilities.

Customer and regulatory authority's representatives are allowed access to GM Nameplate's QMS documentation.

4.2.3 Medical Device File

For each medical device product, GM Nameplate establishes and maintains a Device Master Record file* that includes documents defining:

a) Product specifications including appropriate customer drawings and specifications;
b) Production process specifications, methods and equipment used, handling specifications, and environmental conditions requirements, when required;
c) Monitoring and measurement activities;
d) Acceptance criteria for the products provided by the customer; and
e) Packaging, labeling, storage and shipping specifications.

The job ticket and associated test, inspection, and certification documents constitute the medical device quality manufacturing plan or “Device Master Record”.

*GMN is a contract manufacturer of medical device components and does not design, develop, sell, distribute, install or service finished medical devices to end users. Therefore, any information related to these activities including information related to the medical device’s general description, intended use/purpose, labelling and instructions for use is not provided by customers to GMN, and is therefore not contained in the DMR. In addition, customers do not provide GMN with confidential health information and therefore such information is not included in the DMR.

4.2.4 Control of Documents

GM Nameplate has established and maintains documented procedures for creation, review and approval, change control, and distribution of all documents and records required by the QMS.

All controlled documents are:

a) Reviewed for adequacy, and approval electronically by authorized personnel before issue,
b) Clearly identify the changes,
c) Reviewed for changes to documents and approved prior to use,
d) Written legibly and are readily identifiable, and
e) Available at the point of use.

Document control at GM Nameplate ensures that all obsolete documents are removed from all points of issue or use promptly and archived in appropriate location.

A master list or equivalent document control procedure are issued by document control to identify the distribution and current revision status of documents.

Documents applicable to control requirements at GM Nameplate that are generated from external origins (industry and international standards, customer specifications, and customer supplied drawing) are also included in the document control system.

Documents of external origin are periodically reviewed to assure the most recent versions are in use.

A copy of the obsolete document is retained for a period of time that has been defined in 00-BMS-003, 2.1. This period ensures that documents to which medical devices have been manufactured and tested are available as defined by the organization, or as specified by relevant regulatory requirements.

4.2.5 Control of Records

GM Nameplate maintains and controls records to provide evidence of conformance to requirements and evidence of the effective operation of our QMS. Documented procedures have been established to ensure that records are legible, readily identifiable, and retrievable. Controls are defined for the identification, storage, security, integrity, protection, retrieval, and disposition of records in 00-QA-105, Record Control.

Records are retained for a minimum of 3 years, or as otherwise specified by customer contract or regulatory requirements. As a contract manufacturer, GM Nameplate produces products to be incorporated into customers' medical devices and is therefore is not privy to the planned lifetime of these medical devices. As a result, customer or regulatory requirements determine record retention requirements.

When completed forms are retained as records, the forms are identified with a title, form number, revision date and/or number when applicable, or be pictured within a procedure or work instruction.

Section 4 Reference Documents:

- 00-BMS-003, 2.1 Document Control
- 00-DOC-001, Document Control
- 00-QA-105, Record Control
- ISO13485:2016 Medical devices-Quality management system-Requirements for regulatory purposes

SECTION 5: MANAGEMENT RESPONSIBILITY

5.1 Management Commitment

GM Nameplate's executive management is committed to the development, implementation, and maintaining the effectiveness of the QMS by:

a) Communicating to all members of the organization the importance of meeting customer, statutory and regulatory requirements,

b) Establishing the quality policy and objectives,

c) Ensuring that quality objectives are established,

d) Conducting periodic management reviews of the QMS, and

e) Ensuring that the necessary resources are available.

5.2 Customer Focus

Executive management ensures that customer requirements are determined and met with the goal of increasing customer satisfaction. Customer requirements are determined, and satisfaction is measured through our product realization and measurement, analysis and improvement processes and procedures.

Executive management ensures that product conformity and on-time delivery are measured and that appropriate actions are taken if planned results are not or will not be, achieved. As quality metrics are subject to change from time to time, reference to specific measurements can be found in management review records for each division of the corporation.

5.3 Quality Policy

Our quality policy expresses our commitment to meet or exceed customer requirements and expectations by maintaining the effectiveness of our quality system. The policy establishes a framework by which we establish and review quality objectives and is periodically reviewed by executive management to ensure its continuing suitability. Executive management ensures that the policy is communicated and understood throughout the organization.

5.4 Planning

Executive management ensures that quality objectives are established and that the QMS is planned to ensure that the quality objectives are met.

5.4.1 Quality Objectives

Measurable quality objectives are established at the appropriate functions throughout the organization that are relevant in supporting the quality policy, meeting the

requirements for products and processes, improving quality and performance, and maintaining and enhancing customer satisfaction.

These objectives, which represent all departments and employees of the company, measure the effectiveness of the QMS relative to the quality policy.

As each division of GM Nameplate varies in processes and products, they also may vary in quality objectives and target metrics. As quality metrics are subject to change from time to time, reference to specific measurements can be found in the records for Management Review for each division of the corporation.

5.4.2 Quality Management System Planning

The QMS is planned to define the processes needed to meet the quality objectives and support the quality policy. QMS changes are evaluated and planned accordingly during management review to ensure that its integrity is maintained.

5.5 Responsibility, Authority, and Communication

The CEO delegates the Corporate Director of Quality and Regulatory as corporate management representative for ensuring that the QMS at all divisions satisfies the requirements of the appropriate QMS standard(s).

The quality assurance manager/director for each division of GM Nameplate serves as management representative for their site. The site management representative is responsible for maintaining total compliance with the corporate QMS as well as the monitoring and control of product quality. The management representative reports to the division president and the Corporate Director of Quality and Regulatory Affairs.

Each employee of GM Nameplate is responsible for ensuring:

a) Applicable policies and procedures are followed within their work area,

b) Any process creating non-conforming product is stopped until corrective action is taken,

c) Procedures, which are undefined or fail to satisfy customer requirements, are identified for corrective action,

d) Principles and methods of continual improvement are regularly applied to processes.

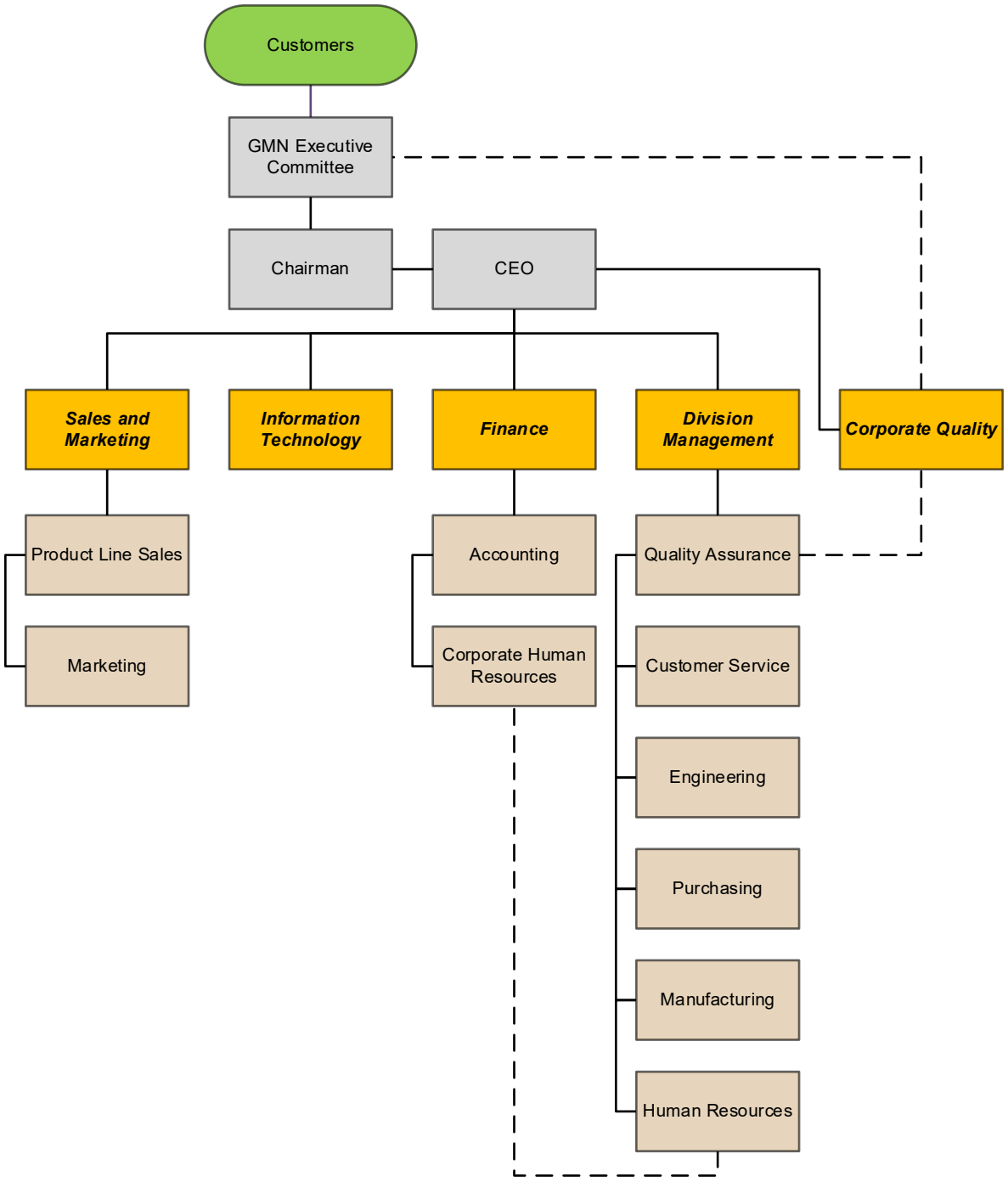


Figure 3 – Corporate Organization Chart

5.5.2 Management Representative

The Quality Assurance Manager for each certified division of GM Nameplate serves as site management representative and has the responsibility and authority for:

a) Ensuring that the processes and requirements of the QMS are well defined, implemented and maintained at the site,

b) Reporting on the performance of the QMS to executive management for review and as a basis for improvement of the QMS,

c) Ensuring that awareness of regulatory, QMS and customer requirements is promoted throughout the division.

d) The organizational freedom and unrestricted access to top management to resolve matters pertaining to quality.

Management representatives also acts as a liaison with external parties on matters related to the QMS.

5.5.3 Internal Communication

Executive management ensures that processes for communicating information concerning the QMS are established throughout the organization. Communication includes information regarding:

a) Quality policies,

b) Quality objectives and requirement,

c) Effectiveness of the QMS.

Communication between functions performing specific QMS activities is defined in the level 3 work instructions (see matrices in appendices) for those activities. Communication methods also include:

a) Management-led employee meetings,

b) Training sessions,

c) Internal publications, bulletin boards, email.

5.6 Management Review

5.6.1 General

The QMS is reviewed by executive management at documented planned intervals to ensure it continuing suitability, adequacy, and effectiveness. Additionally, management reviews the quality systems to identify the needs for changes or improvements, including the quality policy and quality objectives. Records of these reviews are maintained.

The quality assurance manager/director schedules and maintains records of each management review meeting for their respective division.

5.6.2 Review Input

Management review input include but are not limited to information on:

a) Results of audits

b) Customer feedback, including customer complaints

c) Process performance and product conformity

d) Status of preventive and corrective actions

e) Follow-up actions from previous management reviews

f) Changes that could affect the QMS

g) Recommendations for improvement

h) New or revised regulatory requirements, and

i) Regulatory reporting activities.

5.6.3 Review Output

The outputs from the management review are included but not limited to any decisions and actions related to the following:

a) Improvement needed to maintain the effectiveness of the QMS and its processes,

b) Improvement of product related to customer requirements, and

c) Resource needs.

Section 5 Reference Documents:
- 00-QA-103, Management Review 00-BMS-003,
- 2.8 Management Planning and Review
- 00-QA-103, Management Review
- ISO13485:2016 Medical devices -Quality management system-Requirements for regulatory purposes

SECTION 6: RESOURCE MANAGEMENT

6.1 Provision of Resources

GM Nameplate determines and provides the resources to implement and maintain the QMS; and to maintain the effectiveness and meet regulatory and customer requirements.

6.2 Human Resources

6.2.1 General

All personnel performing work affecting conformity to product requirements are ensured to be competent on the bases of appropriate education, training, skills and experience as needed to successfully fulfill their responsibilities.

6.2.2 Competence, Awareness, and Training

GM Nameplate documented procedures requires competence for personnel performing activities affecting product quality and their training requirements.

A training certification process is used to train, certify, and record that employees have been properly trained and are deemed competent to the documented processes, procedures and work instructions within the scope of the QMS.

Training is periodically evaluated to assess its effectiveness in meeting goals and requirements and to identify further actions needed to achieve or maintain the necessary competence. Methods used to evaluate training effectiveness include internal and external audits, employee performance reviews, and quality and productivity data.

The appropriate records of training, education, skills, and experience are maintained by the Human Resources department or Quality Assurance.

6.3 Infrastructure

The infrastructure needed to assure conformance to quality requirements, prevent product mix-up and ensure orderly handling of product is determined, documented, provided, and maintained. Maintenance activities, including methods and intervals are defined in divisional level 3 documents. Records of maintenance activities are maintained per 00-QA-105. Infrastructure includes, as applicable:

a) Buildings, workspaces and associated utilities,

b) Process equipment (hardware and software), and

c) Supporting services (communication, transport, information systems, etc.).

6.4 Work Environment and Contamination Control

6.4.1 GMN manages and maintains the work environment in accordance with all general health and safety requirements, employee agreements, and laws and regulations. Work environment requirements that exceed GMN's normal manufacturing conditions are documented.

GMN has documented the requirements for health, cleanliness and clothing of personnel when contact between such personnel and the product or work environment adversely affects the quality of the product. The requirements for the above are documented in the appropriate level 3 branch specific documents.

In the case it is determined the work environment conditions could have a possible adverse effect on product quality; GMN will document the requirements for the work environment conditions along with the controlling and monitoring of these conditions.

Employees who are required to work temporarily under special environmental conditions are competent or supervised by a competent employee.

There are no special requirements for cleanliness in our product lines for medical products. GMN normal manufacturing conditions are adequate.

When GMN hires personnel on a temporary basis; it is the responsibility of the applicable department manager to train these persons on the environmental conditions within the work environment. Records of this training are documented in accordance with 00-BMS-003, 2.3.

6.4.2 Contaminated or potentially contaminated product is identified, segregated, contained and controlled per nonconforming product handling procedures in order to prevent the contaminated product from contaminating other materials, products and equipment, the work environment and personnel.

There are no requirements for control of microorganisms or particulate matter because GM Nameplate does not manufacture sterile medical device components or finished devices.

Section 6 Reference Documents

- 00-BMS-003, 2.2 Hiring
- 00-BMS-003, 2.3, Training
- 00-QA-130, Handling Nonconforming Product
- 00-QA-130.1, Dispositioning Nonconforming Product
- ISO13485:2016 Medical devices -Quality management system-Requirements for regulatory purposes

SECTION 7: PRODUCT REALIZATION

7.1 Planning of Product Realization

GM Nameplate's customers develop the design and finished device specifications and requirements for acceptance.

GM Nameplate plans and develops the processes needed for product realization through the preparation of Device Master Record (Job Ticket), which includes production steps, equipment requirements, and quality requirements consistent with the QMS.

Product realization planning is controlled and documented through the interdepartmental participation. This process includes defining:

a) Resource requirements specific to the product, including infrastructure and work environment

b) Product and personnel safety,

c) Reliability, availability and maintainability,

d) Monitoring/measuring requirements,

e) Manufacturability and inspection methodologies,

f) Suitability of parts and materials used in the product, and

g) Developing the processes, equipment, handling, storage, shipping and traceability activities in accordance with customer requirements, customer technical specifications, and QMS requirements,

h) Quality objectives and requirements for products.

i) Any documentation needed, including records.

The primary output of this process is the Device Master Record (job ticket), which includes the basic manufacturing and quality plan. Output may also include additional work instructions, inspection, and test plans, project plans and control plans.

Risk management activities, including risk assessments are documented and records maintained throughout the product realization process. Products manufactured at GM Nameplate are components to a medical device and there is often limited information available to allow for product risk management activities. Most of the times the intended use of products is not known as the design and specifications for these devices are provided from external sources. However, GM Nameplate performs process risk assessment during the product realization planning stage to identify risks associated with the production process.

The effectiveness of risk management of GM Nameplate products is monitored through returned materials or complaints processes or activities and subsequent trend analysis of data.

7.2 Customer-Related Processes

7.2.1 Determination of Requirements Related to the Product

GM Nameplate maintains documented procedures to control activities associated with review of customer orders including the requirements for delivery and post-delivery activities.

Requirements related to the product are determined during Request for Quotation (RFQ) and contract review processes, involving Sales, Design Engineering, Process Engineering, Quality Engineering, Customer Service, and other functions as appropriate.

The requirements identified are:

a) Specified by the customer, including delivery and post-delivery requirements,

b) Not specified by the customer but necessary for the specified or intended use of the product,

c) Related to statutory and regulatory requirements, and

d) Any additional requirements identified by GM Nameplate.

7.2.2 Review of Requirements Related to the Products

Requirements related to the product are reviewed during Request for Quotation and Contract Review processes prior to our commitment to supply a product to the customer. Customer Service is responsible to review or coordinate the review of request for quotations, purchase orders, and contracts. The Contract Review process will ensure that:

a) Customer and product requirements are adequately defined and documented. Where no written statement of requirement is available, GM Nameplate ensures that the order requirements are confirmed, agreed, and documented before acceptance,

b) Any differences in the requirements are resolved,

c) GM Nameplate has the capability to meet contractual requirements,

d) Special requirements of the product are determined, and

e) Applicable regulatory requirements are met.

When product or contract requirements are changed, amendments are made to the relevant documents and are transferred to the concerned functions within the organization. These processes are defined in documented procedures. Records of contract review are maintained.

7.2.3 Customer Communication

GM Nameplate establishes effective methods of communication with our customers, including determining customer requirements, product information, handling of customer inquiries, orders and contracts, and customer feedback including customer complaints.

GM Nameplate further has a communication method established for customer feedback, complaints or return of any nonconforming materials and advisory notices.

7.3 Design and Development requirements are excluded

The design and development requirements for products do not apply to GM Nameplate. Products at GM Nameplate are manufactured to customers' design and specifications. Customers are responsible for controlling their product design and evaluating risks associated with those designs.

7.4 Purchasing

7.4.1 Purchasing Process

GM Nameplate ensures that all purchased goods and services utilized in the manufacture of GM Nameplate products conform to specified requirements. Through a controlled purchasing process and close working relationships with our suppliers, materials are purchased at the best possible quality, cost, and delivery.

Suppliers are evaluated and selected based upon established criteria. These criteria include:

a) The supplier's ability to provide products and services that meet QMS requirements,

b) Supplier performance,

c) The effect of the purchased product or service upon the quality of the products manufactured by GM Nameplate, and

d) The risks associated with the products manufactured by GM Nameplate.

Purchasing at GM Nameplate maintains list of suppliers, and records of approved supplier evaluation, selection, monitoring and actions taken for performance deficiencies, including re-evaluation.

Monitoring of suppliers, including supplier performance and non-fulfillment of purchasing requirements is planned and implemented. The results of monitoring are proportionate to the risks associated with the purchased products and service, applicable regulatory requirements, and include a determination of the need to re-evaluate suppliers.

7.4.2 Purchasing Information

Purchasing documents contain the information necessary to describe the product to be purchased. Where appropriate, purchasing information includes:

a) Requirements for the approval of product, procedures, processes and equipment,

b) Requirements for qualification of personnel,

c) QMS requirements.

d) Identification and revision status of the product, and all applicable specifications, drawings and other relevant data, and

e) Change notification and verification

f) Written supplier quality agreements that contain provisions for the supplier to notify GM Nameplate of any changes to purchased product that affect the ability of the purchased product to conform to purchasing requirements.

Purchasing documents are reviewed for adequacy prior to their communication to the supplier. Records and documents of relevant purchasing information are maintained for traceability purposes.

7.4.3 Verification of Purchased Product or Service

GM Nameplate maintains documented procedures assuring that incoming materials are inspected and meet specified purchase requirements. Purchased product is verified to ensure that it meets the specified purchase requirements. The extent of verification activities is based upon supplier evaluation results and proportionate to the risks associated with the purchased product. Verification may include inspection, review of data, and other activities on the part of the GM Nameplate or our supplier. Where GM Nameplate or our customer intends to perform verification at the supplier's premises, the intended verification arrangements and methods are stated in the purchase order.

In the event materials or components are rejected, the procedures assure the segregation of this material. Records of receiving and verification activities are maintained.

When GM Nameplate becomes aware of changes to purchased product, the changes are reviewed to determine whether there is any affect upon product-related QMS processes or products manufactured.

7.5 Production and Service Provision

7.5.1 Control of Production and Service Provision

GM Nameplate has developed processes and procedures to ensure that all aspects of production activities are controlled and validated, and that product is properly identified and protected throughout manufacturing and delivery.

Procedures are maintained for planning and carrying out production under controlled conditions, including:

a) Product characteristics information is provided that describe the characteristics of the product,

b) Work instructions describing the performance of the process are available as necessary to ensure safety, quality, and compliance with regulatory requirements,

c) Equipment suitable for the production of the product or performance is used, including qualification of infrastructure,

d) Availability and use of monitoring and measuring equipment is used to monitor and measure processes and product,

e) Implementation of monitoring and measuring equipment is used to monitor and measure processes and product,

f) Release and delivery activities are defined for the release and delivery of the product, receipt of customer returned product (RMA) and where applicable, post-delivery activities,

g) Accountability is maintained of all products during manufacturing,

h) Evidence that all production and inspection/verification operations have been completed as planned, of as otherwise documented and authorized,

i) Provisions for the prevention, detection and removal of foreign objects,

j) Utilities, such as water, compressed air, electricity and chemical products, are monitored and controlled where they affect product quality,

k) Criteria for workmanship are provided in the clearest practical way,

l) Process controls and control plans are established where key characteristics have been identified,

m) In-process verification points are identified when adequate verification of conformance cannot be performed at a later stage of production,

n) Tooling is designed, manufactured and used so that variable measurements of the product can be made, particularly for key characteristics,

o) Special processes, where the resulting output cannot be verified by subsequent monitoring and measurement, are validated.

p) Implementation of product labelling and packaging activities.

Each order of a product has a unique identification number which is used for traceability purposes. Additionally, each production record has the information regarding the amount manufactured.

7.5.2 Cleanliness of Product requirements are not applicable.

7.5.3 Installation Activities requirements are not applicable.

7.5.4 Servicing Activities requirements are not applicable.

7.5.5 Particular Requirements for Sterile Medical Devices requirements are not applicable.

7.5.6 Validation of Processes for Production and Service Provision requirements are not applicable.

7.5.7 Particular Requirements for Validation of Processes for Sterilization and Sterile Barrier Systems are not applicable.

7.5.8 Identification

Product is identified, and traceability is maintained throughout the manufacturing cycle. Procedures are maintained to provide for:

a) Identification of raw materials and purchased components, including those stored in inventory or released to work orders. Traceability of key raw materials and purchased components, as defined by GM Nameplate procedures, is maintained.

b) Identification of each production order with a unique number that serves as a lot number. The product and its associated work order ticket are identified with this number throughout production, inspection and test, packaging and shipment. Individual products may be uniquely identified per customer requirement.

c) The status of product with respect to monitoring, measurement, inspection and test requirements is maintained throughout production and storage to ensure that only product that has passed all of the planned inspection and test activities or released under authorized concession is available for shipment. Each process is signed or initialed when completed. If finished product is entered into inventory, the inventory record and labeling identifies the lot number. All information specific to finished product is maintained in production records by lot number.

d) Order tracking, accomplished with a barcode routing system recording order movement from station to station.

e) Upon completion of production, products are packaged and identified by customer purchase order number and part number.

f) Maintenance of the identification of the configuration of the product through work order tickets and controlled drawings, specifications and other documentation.

g) Records are maintained to document any differences in the actual configuration and the agreed upon configuration.

h) Documented procedures and controls where acceptance authority media are used i.e. stamps, electronic signatures or passwords, etc.

7.5.9 Traceability

7.5.9.1 Traceability—General

GM Nameplate's documented procedure provides details on traceability of the product. In general, GM Nameplate provides for the following levels of traceability:

a) Identification of the product so that the identification and traceability are maintained throughout the product life,

b) Traceability of all of the products manufactured from the same batch, including the destination (delivery, scrap) of all of the products from the same batch,

c) Traceability of components in an assembly, and

d) A sequential record of the manufacturing and inspection processes used in the production of the product.

7.5.9.2 Particular Requirements for Implantable Medical Devices requirements are not applicable.

7.5.10 Customer Property

GM Nameplate occasionally works with customer owned and supplied materials and equipment, and also intellectual property e.g. specifications, drawings, digital media and personal data. Customer property is verified, stored, and maintained as specified by the customer or, when not specified, in the same manner as GM Nameplate property. Any property that is lost, damaged or otherwise found to be unsuitable for use is reported to the customer and records are maintained.

7.5.11 Preservation of Product

GM Nameplate maintains documented procedures for preserving the conformity and quality of products from the time of receipt during the internal processing and delivery to our customers. Requirements for preservation of product are consistent with product specifications and contract and regulatory requirement.

Procedures include provisions for identification, handling, storage, packaging, protecting from alteration and damage, and delivery, as well as methods for controlling products or raw materials with limited shelf life.

In general, products manufactured by GM Nameplate are not susceptible to damage or deterioration due to ambient environmental conditions therefore no special storage conditions are typically required. However, when products do require special storage conditions where packaging alone cannot provide preservation a procedure or work instruction (including associated records) is documented to define the parameters of the controls implemented.

7.6 Control of Monitoring and Measuring Devices

GM Nameplate determines the monitoring and measurement to be undertaken and the monitoring and measurement devices required to provide evidence of conformity of products to determined requirements.

GM Nameplate maintains documented procedures to ensure that monitoring and measurement are adequate to provide evidence of product conformity to the specification and requirements. This includes details of the equipment type, unique identification, location, frequency of checks, check method and acceptance criteria.

Devices used to monitor or measure product, including test software or comparative references are controlled by:

a) Determining required monitoring/measurement and suitable devices and ensuring consistency with monitoring and measurement requirements,

b) Device calibration at specified intervals against of NIST-traceable or equivalent standards. Where no such standards exist, the basis used for calibration is documented. Where appropriate, maintenance activities are performed as part of device calibration,

c) Documenting any required adjustments and recording,

d) Identifying calibration status,

e) Safeguarding devices from inadvertent adjustments,

f) Protection from damage and deterioration, and

g) Assess and document the validity of product tested with equipment found to be out of calibration, and take corrective action, as required.

Records of measurement and monitoring equipment calibration, recalibration, and adjustments are maintained. Equipment that cannot be calibrated or is designated as “For Reference Only” are labeled as such.

Section 7 Reference Documents

- 00-BMS-003, 1.0 Quoting
- 00-BMS-003, 1.1 Order Processing
- 00-BMS-003, 1.3 Advanced Product Quality Planning
- 00-BMS-003, 1.4 Manufacturing
- 00-BMS-003, 1.5 Inspection and Packaging
- 00-BMS-003, 1.6 Product Audit and Ship
- 00-BMS-003, 2.4 Purchasing
- 00-BMS-003, 2.5 Receiving Inspection
- 00-BMS-003, 2.6 Calibration
- 00-QA-130, Handling Nonconforming Product
- 00-QA-130.1, Dispositioning Nonconforming Product

- 00-QA-106, Corrective and Preventive Action
- ISO13485:2016 Medical devices -Quality management system-Requirements for regulatory purposes

SECTION 8: MEASUREMENT, ANALYSIS, AND IMPROVEMENT

8.1 General

GM Nameplate maintains documented procedures for development and implementation of plans for monitoring, measurement, analysis and improvement processes using appropriate statistical tools and techniques to:

a) Demonstrate the conformance of product requirements,

b) Ensure the conformance of our QMS,

c) Maintain the effectiveness of the QMS.

8.2 Monitoring and Measurement

8.2.1 Feedback

GM Nameplate monitors information about QMS effectiveness specifically related to post-production activities. These activities address our customer's perception as to whether we have met their requirements. Documented procedures define the methods for obtaining and using this information. Methods include:

a) Customer surveys. Corporate Sales and Marketing coordinates with each division of GM Nameplate to perform annual customer surveys,

b) Customer feedback and complaints. A customer comment form is maintained on the GM Nameplate website. Customer complaints received through other means are recorded in the eQMS.

c) Customer returned products,

d) Customer-supplied performance reports,

These records are periodically reviewed and monitored for possible trending that may evidence recurring or consistent problems or issues. These feedback inputs are used to provide early warning of any quality problems and drives corrective and preventive actions that may need to be taken.

GM Nameplate also monitors information related to production activities as defined in 8.4, Analysis of Data.

Information gathered from the feedback processed is reviewed during Management Review and provides an input to risk management and proposed changes to QMS processes.

8.2.2 Complaint Handling

Documented procedures define requirements and responsibilities for receiving, recording, evaluating and investigating customer complaints, reporting to regulatory authorities and handling of complaint-related product.

When investigation determines that the activities outside GM Nameplate premises contributed to the customer complaint, relevant information is communicated between GM Nameplate and the external party involved.

Documented procedures stipulate that customer complaints are followed by corrective and/or preventive action and if not, the justification is recorded. Records of complaint handling, including investigations and resulting corrective actions are maintained.

8.2.3 Reporting to Regulatory Authorities

GM Nameplate maintains a documented procedure for the issuance of advisory notices. Records of the issuance of advisory notices are maintained. As an organization, GM Nameplate does not receive adverse event reports from end users because it does not manufacture finished medical devices.

8.2.4 Internal Audit

Internal audits are conducted on planned intervals to determine if the QMS complies with the required standard, customer, and/or regulatory requirements and to determine if it is effectively implemented and maintained.

Audit schedules are based on considerations of the importance of processes to the objectives of GM Nameplate, and the results of previous audits.

Audits are carried out by competent, trained personnel who are not directly responsible for the audited activity. The quality assurance manager may delegate an audit to any trained employee at the company. Internal audits may also be subcontracted to a qualified third-party organization.

Management is responsible for ensuring that any necessary corrective actions are taken in a timely manner and following up to ensure the elimination of detected nonconformities identified during the internal audit, and the effectiveness of these action.

Records of audits and corrective/preventive actions are maintained.

8.2.5 Monitoring and Measurement of Processes

QMS processes are monitored and measured to determine ability of the processes to achieve the planned objectives. Methods used to monitor and measure processes include:

a) Customer satisfactions results,

b) Internal audits,

c) Product quality performance measurements,

d) Process efficiency measurements,

e) On-time delivery performance.

Corrections and corrective actions are taken commensurate to the effect of the process nonconformance on the conformity of the product when the processes do not achieve the planned results. See Management Review records for specific divisional metrics and results.

8.2.6 Product Monitoring and Measurement of Product—General Requirements

Product characteristics are monitored and measured to verify that product requirements have been met. An appropriate selection of both variable and attribute characteristics is monitored and measured at locations established during the planning of product realization processes. Work instructions specify inspection at each location. The work order ticket and part drawings convey product specific inspection requirements.

Records of inspections and testing are maintained as evidence of conformity with the acceptance criteria. Records identify the person authorizing release of the product. Product is not released until all of the planned activities for product realization have been satisfactorily completed. Records identify the test equipment used to perform measurement activities per customer requirement.

GM Nameplates does not manufacture, assemble or distribute active implantable devices or implantable devices.

8.3 Control of Nonconforming Product

8.3.1 General

Documented procedures define the control of product that is found nonconforming, detected at any stage of manufacturing from incoming inspection through shipping, and product returned by the customer. These procedures define the responsibilities and authorities for identification, documentation, segregation, evaluation and disposition of nonconforming product. Evaluation includes the need for investigation and notification to an external party when an investigation determines that an external party is responsible for the nonconformity. Controls prevent the unintended use or delivery of nonconforming product, including raw materials, components, subassemblies, and finished items.

Records of nonconformities, including evaluation, investigation, rationale for disposition and subsequent actions taken, including concessions are maintained.

8.3.2 Actions in Response to Nonconforming Product Detected Before Delivery

Documented procedures define the requirements for nonconforming product identification, containment, segregation and potential correction.

Nonconforming product may only be accepted by the customer under concession if the customer provides documented justification and approval, and applicable regulatory requirements are met. Records of the concession includes the identity of the person authorizing the concession are maintained.

8.3.3 Action in Response to Nonconforming Product Detected After Delivery

When non-conforming product is detected after delivery or use has started, GM Nameplate takes appropriate actions to the effects, or potential effects, of the nonconformity. Delivered nonconforming product is reported to the customer in a timely manner.

Documented procedures capable of being implemented at any time define the responsibilities and requirements for the issuance of advisory notices. Records of the issuance of advisory notices are maintained.

8.3.4 Rework

Dispositions applied may be: rework, use as is (only when the nonconformity does not result in a departure from the customer-specified requirements or is authorized by customer), repair, scrap or return to supplier.

Nonconforming product that can reworked is subject to re-verification and the same type of inspection and approval as the original job to ensure that the reworked product meets the acceptance criteria and applicable regulatory requirements.

Prior to authorization and approval of reworked products, potential adverse effect of the rework on the product will be identified and documented. All reworks are documented on appropriate job ticket or work instruction(s) and undergo the same review and approval process as the original job ticket and/or work instruction(s). Reworked documents are maintained with the original ticket or batch for that product.

Records of rework are maintained on the job ticket.

8.4 Analysis of Data

Data is collected and analyzed to evaluate the suitability and effectiveness of the QMS and to evaluate where improvement of the effectiveness of the QMS can be made. When statistical techniques are used to analyze data, the extent of their use is documented in the applicable procedure or work instruction.

Categories of data collected and analyzed include:

a) Product Quality – Quality Assurance ensures that quality data, including the costs of nonconformance, are collected and reported. Quality reports are reviewed by executive and departmental management. Quality data are also analyzed for trends and presented in Management Review meetings by Quality Assurance 00-BMS-003, 2.8.

b) Process Performance – Data related to process performance, including variations from planned efficiencies and schedules, are collected, and reviewed by department managers. Performance and trends are compared to appropriate goals and company benchmarks. Department managers analyze variances, identify problems, and implement solutions to maintain performance goals and improve performance.

c) Supplier Performance – Purchasing and Quality Assurance ensure that supplier performance data are collected and reported per 00-BMS-003, 2.4.

   Performance data include on-time delivery and conformance to quality requirements. Purchasing and Quality Assurance analyze supplier performance and take appropriate actions to maintain and improve performance goals.

d) Customer feedback – Data related to customer satisfaction levels and complaints are collected by Sales and Marketing, Customer Service and Quality Assurance, and reviewed by executive management.

e) Audits.

Records of the results from data analysis are maintained and used as inputs for Management Review and Corrective Action processes. Quality data provided as inputs for management review are retained according to the procedures established for the associated process i.e. complaint handling, Nonconforming product, corrective and preventive action, and audits, etc.

8.5 Improvement

8.5.1 General

Improvement of the QMS is driven through the quality policy and quality objectives. Opportunities for improvement are identified through management review, audits, corrective and preventive action processes, and analysis of data. Improvements are monitored and evaluated for effectiveness of the QMS.

8.5.2 Corrective Action

GM Nameplate maintains a documented procedure, 00-QA-106, to ensure that actions are taken to eliminate the cause of nonconformities and follow up action are performed to ensure that action taken will effectively prevent recurrence. The need for corrective action, actions considered and actions implemented are commensurate with the magnitude and risks associated with the nonconformities and proportionate to the effects fo the nonconformities. Verification includes determining that the corrective action did not adversely affect the ability to meet applicable regulatory requirements. The corrective action may apply to suppliers, product quality and production process, customer complaints and internal audit findings, and are taken without undue delay.

Records of the results of the investigation, corrective actions taken, and follow-up actions are maintained. Results of Corrective Actions and their effectiveness are reviewed by management in Management Review meetings.

8.5.3 Preventive Action

Preventive actions are taken to prevent potential nonconformities as documented in 00-QA-106. Actions taken are proportionate to the effects of the potential problems. The determination of need for preventive action includes review and analysis of processes, quality data, trends, customer complaints and feedback, and audit results.

Verification of preventive actions includes determining that the preventive action did not adversely affect the ability to meet applicable regulatory requirements.

Records of the results of the investigation, preventive actions taken, and follow-up actions are maintained. Results of Preventive Actions and their effectiveness are reviewed by executive management in management review meetings.

Section 8 Reference Documents

- 00-BMS-003, 2.8 Management Planning and Review
- 00-BMS-003, 2.4 Purchasing
- 00-BMS-003, 1.5 Inspection and Packaging
- 00-BMS-003, 1.6 Product Audit and Ship
- 00-QA-112, Product Recall and Advisory Notice
- 00-BMS-003, Receiving Inspection
- 00-BMS-003, 2.7 Internal Audits
- 00-BMS-003, 1.7 Dispositioning Nonconforming Product
- 00-QA-130, Handling Nonconforming Product
- 00-QA-130.1, Dispositioning Nonconforming Product
- 00-QA-130.3, Customer Returned Product
- 00-QA-106, Corrective and Preventive Action
- ISO13485:2016 Medical devices -Quality management system-Requirements for regulatory purposes