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REVISION HISTORY	
REV	DESCRIPTION OF CHANGE
8	<ul style="list-style-type: none"> - Add Therapeutic Goods (Medical Devices) Regulations 2002 in Section 2.2 Compliance to regulation
9	<ul style="list-style-type: none"> - Correct the clause number in Section 2.3 from Clause 7.5 to 7.5.3 - Update table B HSO Processes. Remove Product Design and development and Production. The clause related to design control and product shall be input in Product Realization. Update list of clause in Product Realization. - Section 4.2.8 – Update to reference Medical Device File to HSO's DMR - Revise QM-16-001 A1 Medical Device file to reference to OPS-18-080 SMR-IN Device Master Record (common) index - Revise QM-16-002 A2 to reference Medical device file requirement to HSO's DMR - Section 7.3.3 – Add point 'Decide on the project pathway' - QMS-16-001 A1 – Section 7 Design Control, add product life cycle management execution guidance
10	<ul style="list-style-type: none"> - Section 2.1 GHQ – Add design control project management, design assurance as part of the activity involved - Section 2.1 HMSP – Add process development as part of the activity involved - Section 2.1 HSOE – now covered by the scope of this Quality Manual - Section 4.1.2 – Quality Process Plan replaces former PDCA based figure - Revise Section 4.2.6 'English shall be the official language for all QMS documents and records/ reports. Except, for whatever potential conflict or disagreement exists relate to technical contents on including any quality records/ report that translated from its original language to English, the decision making shall be made on the version of original language' to 'English shall be the official language for all QMS documents and records/ reports including any quality records/ report that were translated from its original language to English.' - Inserted: Section 4.2.5 introduces the idea of Global Policies - Section 4.2.6 → 4.2.7 – Remove the phrase with sentence 'when in doubt' from the sentence 'It is the responsibilities of the reviewers and approver to verify the accuracy of the translated (in English) quality records/report.' Document structures now includes the Global Policies
11	<ul style="list-style-type: none"> - Correct Korean regulations name in Section 2.2
12	<ul style="list-style-type: none"> - Addition of HLAM manufacturing site and Global Distribution center throughout Quality Manual - Clarification in Management Review, HSO Entities - Clarification about outsourcing activities - Update to Quality Policy in Appendix - Minor typo and error corrections
13	<ul style="list-style-type: none"> - Addition of Manufacturing to Outsourcing - Removal of Section 7.3.3 - Adding strategy for regulatory compliance - Adding Communication with CA, NB, Economic operators, Customer - Clearer image of Quality Policy in Appendix
14	<ul style="list-style-type: none"> - Update to new document template - Addition of reference to new Global Glossary form - Added clarification to the strategy for regulatory compliance (art.10(9))
15	<ul style="list-style-type: none"> - Addition of HMLC, HMIN and Ruck to Section 2.1
16	<ul style="list-style-type: none"> - Updated HMLC address and included in Ruck scope for servicing and installation Section 2.1
17	<ul style="list-style-type: none"> - Amend section 2.1 to align EN ISO 13485:2016 & MDSAP scope accordingly to latest certificate & update the scope for each HSO site. - Amend section 4.1.2 to update HSO Business Flow and update Design & Development as outsourced activities to HMRC.

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REVISION HISTORY	
REV	DESCRIPTION OF CHANGE
	<ul style="list-style-type: none">- Amend section 4.2 to update HSO – Global QMS Documentation hierarchy to include list of Global SOPs / WI.- Amend section 7.5.3 and 7.5.4 to include documentation requirements for Installation and Servicing Activities for RUCK, HSOE and HMIN.

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1.0 INTRODUCTION

With more than 70 years of optical product expertise from the HOYA Group and more than 30 years of experience in designing and producing intra-ocular lenses (IOL), HOYA Surgical Optics is one of the largest global IOL focused companies with a mission to improve vision and quality of life for millions of people suffering from cataract. Based on the core tenets of Quality, Trust, Dedication and Attention to Detail, HOYA Surgical Optics develops innovative and high-tech products that offer ease of use, safety and reliability to eye surgeons and ophthalmologists worldwide.

HOYA Surgical Optics is a division of the HOYA Group, a global technology company established in Tokyo, Japan, and the leading supplier of innovative and indispensable high-tech products based on advanced optics technologies. HOYA has over 140 subsidiaries and affiliates, employs over 35,000 people worldwide, and generates 565 billion Japanese Yen (5.3 billion USD) in annual revenue (data from Corporate Profile March 2019).

The HOYA Surgical Optics division comprises out of multiple legal entities that are located throughout Asia, Europe and the United States. The headquarters of the division is located in Singapore at 10, Biopolis Road, Chromos Level 4 #4-01, Singapore 138670, and is part of the legal entity HOYA Medical Singapore Pte. Ltd.

2.0 SCOPE AND EXCLUSION

2.1. Locations and Certification Scope

This HSO Global Quality Management System is designed to fulfill customer needs and expectations, compliance with applicable regulatory and statutory requirements, national and international standards for the following EN ISO 13485:2016 certification scope:

Design and Development, Production and Distribution of Sterile Intraocular Lenses, and Other Non-active Ophthalmologic Devices and Accessories.

Design and Development, Production and Distribution of Accessories for Active Ophthalmologic Surgical Systems

HSO is certified by the Medical Device Single Audit Program (MDSAP) which confirms compliance and satisfy the needs of 5 regulators: FDA, TGA, ANVISA, Health Canada and PMDA. The following MDSAP scope applies for the HSO MDSAP certificate:

Design and Development, Production and Distribution of Sterile Intraocular Lenses, Intraocular Lenses Cartridge and Capsular Tension Ring for the area of Ophthalmology

HSO assigned Hoya Medical Singapore (HMS) to act as “Manufacturer” (legal manufacture) for Europe, Canada and Australia in the framework of the Medical Device Directive (93/42/EEC), the European Medical Device Regulation (EU MDR), the Canadian Medical Device Regulations (SOR/98-282) and the Australian Therapeutic Goods (Medical Devices) Regulations and the European Medical device regulation (EU MDR).

The following inter companies are covered by this HSO Global Quality Management System:

- HOYA Surgical Optics Global Headquarter (HSO – GHQ) located at 10, Biopolis Road, Chromos Level 4, #04-01, Singapore 138670 for design & development of Sterile Intraocular Lens and other Non-active Ophthalmologic Devices and Accessories, design and development, production and distribution of Accessories for Active Ophthalmologic Surgical Systems, management control and post market surveillance.
- Hoya Medical Research Center (HMRC) or alternate named Hoya Medical Japan Technical Centre (HMJTC) located at Helios II Building, 1-12-11 Funado Itabashi-ku, Tokyo 1740041 Japan for design & development of Sterile Intraocular Lens and other Non-active Ophthalmologic Devices and Accessories and specification development.
- HOYA Medical Singapore Pte. Ltd. (HMS) located at 455A Jalan Ahmad Ibrahim Singapore 639939 for process development, process manufacturing, sterilization and distribution activities of Sterile Intraocular Lens and other Non-active Ophthalmologic Devices and Accessories.

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- HOYA Lamphun Ltd. (HLAM) or alternate name HOYA Surgical Optics Thailand (HSOT) located at 75/2 Moo 4 Tambol Banklang, Muang Lamphun 5100, Thailand for process manufacturing, sterilization and distribution activities [of Sterile Intraocular Lens and other Non-active Ophthalmologic Devices and Accessories](#).
- HOYA Lamphun Ltd. Distribution Centre or alternate name Global Distribution Centre (GDC) located at 158/13 Moo 5, Tambol Nongkham, Amphur Siracha, Chonburi 20110 Thailand for distribution of [Sterile Intraocular Lens and other Non-active Ophthalmologic Devices and Accessories](#).
- Hoya Surgical Optics GmbH (HSOE), De-Saint-Exupéry-Straße 10, 60549 Frankfurt am Main, Germany. as EU Importer, Authorized Representative, and Logistics center for Ophthalmic devices, Instruments and Accessories.
- Hoya Surgical Optics Inc (HSOU), 15355 Fairfield Ranch Drive, Chino Hills, CA USA, registered with FDA as USA Complaint File Establishment
- HOYA Medical Logistics Centre (HMLC), Chidori-cho 13, Ichikawa-shi, Chiba, 272-0126, Japan [for distribution of Sterile Intraocular Lens and other Non-active Ophthalmologic Devices and Accessories](#).
- HOYA Medical India PVT Ltd (HMIN) H-9, 2nd Floor, Block B1, Mohan Co-operative Industrial Estate, Mathura Road, New Delhi 110044, India [for distribution of Sterile Intraocular Lens and other Non-active Ophthalmologic Devices and Accessories; distribution, installation and servicing of Active Ophthalmologic Surgical Systems and accessories](#).
- HOYA (Shenzhen) Medical Device Consulting Co, Ltd (HMSH), Room 2603, No 1045 Middle Huaihai Road, Huaihai Plaza, Xuhui District, Shanghai, China (200031) [for distribution of Sterile Intraocular Lens and other Non-active Ophthalmologic Devices and Accessories](#)
- Fritz Ruck Ophthalmologische Systeme GmbH (RUCK), De-Saint-Exupéry-Straße 10, 60549 Frankfurt, Germany (Manufacturing at Ernst-Abbe-Strasse 30 b Eschweiler, 52249 Germany) [for design & development of production and distribution of Accessories for Active Ophthalmologic Surgical Systems](#).

The above entities have to fulfill all applicable elements of the HSO Global Quality Management System described in this Global Quality Manual and have to maintain a formal Quality System Certification as a sole entity or in combination with other entities.

Regional sales and distribution offices, with the exception of HSOE and HSOU have to follow the HSO Global Quality Management System to the extent necessary to interface with the global processes of the HSO Global Quality Management System e.g. customer complaints. However, it is at the discretion of local management whether a formal Quality System Certification will be maintained.

2.2. Strategy for regulatory compliance. Compliance to regulations.

HSO is committed to the highest standards of product safety, intended performance, and regulatory compliance. To achieve this commitment, Hoya has established, documented and implemented an effective QMS to achieve compliance, ensures product safety and performance in accordance with applicable regulatory requirements and to support the continuous improvement of Hoya processes, products, systems as described in this Quality Manual.

The Chief Executive Officer (CEO) of Hoya is the highest level of organization is ultimately responsible for quality and regulatory compliance at Hoya.

CEO assigns a Management representative and Person Responsible for Regulatory Compliance in the organization who is ultimately responsible for execution of strategy for regulatory compliance within the organization.

Strategy for regulatory compliance includes the following key elements:

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- Achieving customer satisfaction and conformity to regulatory requirements during all stages of design, development, production and post production,
- Preventing nonconformity at all stages from design and development through servicing and obsolescence,
- Establishment an effective Quality Management system,
- Establishment of Regulatory intelligence program and effective implementation of new or changed regulatory requirements (regulations, standards, guidelines, common specifications etc).
- Promotion and awareness of regulatory and customer requirements throughout the organization.
- Processes for identification of relevant legal and regulatory requirements, qualification, classification, handling of equivalence, choice of and compliance with conformity assessment procedures
- Compliance with conformity assessment procedures and procedures for management of modifications to the devices covered by the system

Compliance to Regulations.

This Global Quality Manual is divided into sections aligned with the requirements of EN ISO 13485 (2016), further referred to as ISO 13485, and is intended to comply with the following regulations (non-exhaustive list):

- Australian Therapeutic Goods (Medical Devices) Regulations 2002
- US FDA 21 CFR Part 820, Quality System Regulation, (QSR)
- EU Medical Device Directive 93/42/EEC / Medical Device Regulation (MDR) 2017 / 745
- Canadian QMS Compliance - SOR 98/282
- Japan QMS Compliance – PMD
- Brazilian regulation RDC 59
- Chinese National Medical Products Administration (NMPA)
- Korean Ministry of Food and Drug Safety (MFDS) Medical Device Act

Note: full list of applicable regulations and standards is published in MasterControl.

2.3. Exclusions to the Standard

ISO 13485 requirement may be excluded only when the following three conditions are met:

- The requirement must be within ISO 13485 Clause 7 Product Realization (see relevant subsections below);
- The exclusion may not affect our ability, nor absolve us from the responsibility, to provide product that meets specified requirements; and
- The exclusion may not affect our ability to carry out a corrective action impacting the safety of the patient and effectiveness of the product.

Processes which are applicable to the product(s), but which are outsourced, do not qualify for exclusion. They are accounted for in the quality system to ensure control over such outsourced processes.

The Global Management Representative in collaboration with Regional / Site Management representatives is responsible for identifying those requirements of ISO 13485 that do not apply to our organization or products, and to propose to the top management that such requirements be excluded from the scope of the quality system.

The ISO 13485 sections identified below are not applicable for full HSO organization due to the business nature of HSO except several sites as identified below:

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- Section 7.5.3 : Installation activities are not offered to the customer (except for Ruck, HSOE and HMIN).
- Section 7.5.4 : Servicing activities (i.e., repair and maintenance) are not offered to the customer (except for Ruck, HSOE and HMIN).
- Section 7.5.10 : Customer Property, there's no customer property controlling or being used by HSO (except for Ruck).

3.0 ABBREVIATIONS

CEO	: Chief Executive Officer
GMT	: Global Management Team
GHQ	: Global Headquarters
GDC	: Global Distribution Centre
GQM	: Global Quality Manual
HOD	: Head of Department
HSO	: HOYA Surgical Optics i.e. it includes all sites of Hoya
HMJTC	: HOYA Medical Japan Technology Center, responsible for design control and specification development
HMRC	: HOYA Medical Research Center, alternate name for HMJTC
HMSP	: HOYA Medical Singapore, the product Manufacturer
HLAM	: HOYA Lamphun Ltd, the product Manufacturer & Distribution
HSOE	: HOYA Surgical Optics, EMEA
HSOT	: HOYA Surgical Optics, Thailand (an alternative name of HLAM)
HSOU	: HOYA Surgical Optics, Americas
MOB	: Management of Business
PGC	: Pipeline Governance Committee
QA	: Quality Assurance
QMS	: Quality Management System
RA	: Regulatory Affairs

For Definitions, refer to Global Glossary (Form_Appendix-20-232)

4.0 THE QUALITY MANAGEMENT SYSTEM

4.1. General Requirements

4.1.1 Structure of the Quality Management System

In HSO, the Top Management has the executive management responsibilities as stated in ISO 13485, composing of CEO and the GMT, and is responsible for establishing the quality policy that is the basis of the HSO Global Quality Management System. They are also responsible for decision concerning the establishment, documentation, implementation and maintenance of an effective quality management system.

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The Top Management utilizes inputs from the market and the employees to develop new products; improve existing products and enhance the quality management system through the setting of quality objectives.

The Top Management ensures the assigned quality objectives are met by establishing the appropriate organizational structure, defining the responsibility and authority of each function, allocating appropriate and adequate resources and personnel, documenting operational procedures for each activity and managing of all projects on the site.

The QA department is responsible for the verification of implementation and maintenance of the quality management system.

4.1.2 HSO –Business Flow

The HSO Global Quality Management System applies to, and interacts with, all activities pertinent to the quality of a product.

Therefore, all aspects of the HSO business are within the scope of the Quality System. The typical sequence for HSO business is (*see figure 1 HSO Business Flow*):

- Global marketing, product management and regulatory submission strategy
- Product design and development, [product registration](#)
- Purchasing (finished products management)
- Manufacturing (by inter companies and/or Subcontractor)
- Inspection and test (of finished products)
- Warehousing (by inter companies and/ or Subcontractor)
- Sales order processing (by inter companies and/ or Subcontractor)
- Delivery (by inter companies and/ or Subcontractor)
- Monitoring and feedback

All applicable outsourced processes defined for each site and listed in the Approved Supplier List (ASL) that is on file at the QA Department, etc. All outsourced processes are from the approved Subcontractors. Where applicable, Quality and/or Service Level Agreements are in place between HSO and the Subcontractor.

All individual outsourced processes will conform to of the applicable requirements and regulations. Variation in conformance with requirements and regulations between Subcontractor is due to their uniqueness in the services or activities they provide:

- Manufacturing: Manufacturing processes are performed by Subcontractors (internal outsourcing) to the legal manufacturer and are present on the Approved Supplier List (ASL) for HSO. A Quality Agreement is in place between HSO and the Subcontractor
- Warehousing and distribution: All outsourced processes such as storage, distribution and receiving customer feedback are from the approved Subcontractors and listed in Approved Distributor List (ADL) that is on file at the QA Department. Where applicable, Quality and/or Service Level Agreements are in place between HSO and the Subcontractor.
- Consultancy: All consultants that provide services impacting the quality, regulatory that impacts safety of the product are qualified and managed based on the established supplier management process (e.g. Australian Sponsor, Canadian regulatory correspondent)
- Sterilization: EO sterilization is partially performed in house and partially outsourced to the approved supplier “Siam Steri Services. Co, Ltd (“SIS”).
- [Design and development](#): Design and development activities are mainly outsourced to HMRC through internal outsourcing and partly performed by HMSP (GHQ) site (legal manufacturer). Quality agreement and other controls (such as internal audits, management/KPIs review, QMS documents/DV/DR documents approval) are in place to ensure control over design and development activities.

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Figure 1: HSO – Quality Process Plan; gives a schematic representation of the business flow and the interacting activities amongst the various functional groups within the organization and outsourced subcontractors.

- The model describes the core elements of the system and their interrelations including interfaces with subcontractors performing outsourced activities, customer interfaces, top management activities and product realization processes.
- Customer, regulatory requirements, statutory requirements, business plans and organization vision play a significant input into the QMS. Such requirements are translated into a Quality Plan which is rolled out on periodic basis. This Quality plan is then embedded into individual and department objectives and monitored at a regular interval. Adequate resources are provided to support the operation. Products and processes are monitored and measured resulting in quality products.
- Information provided by the customer such as feedback, complaints and order fulfilment are reviewed and monitored to ensure requirements are met and customer is satisfied. Periodic review is conducted by Top Management on the performance of the quality management system for effectiveness and suitability.

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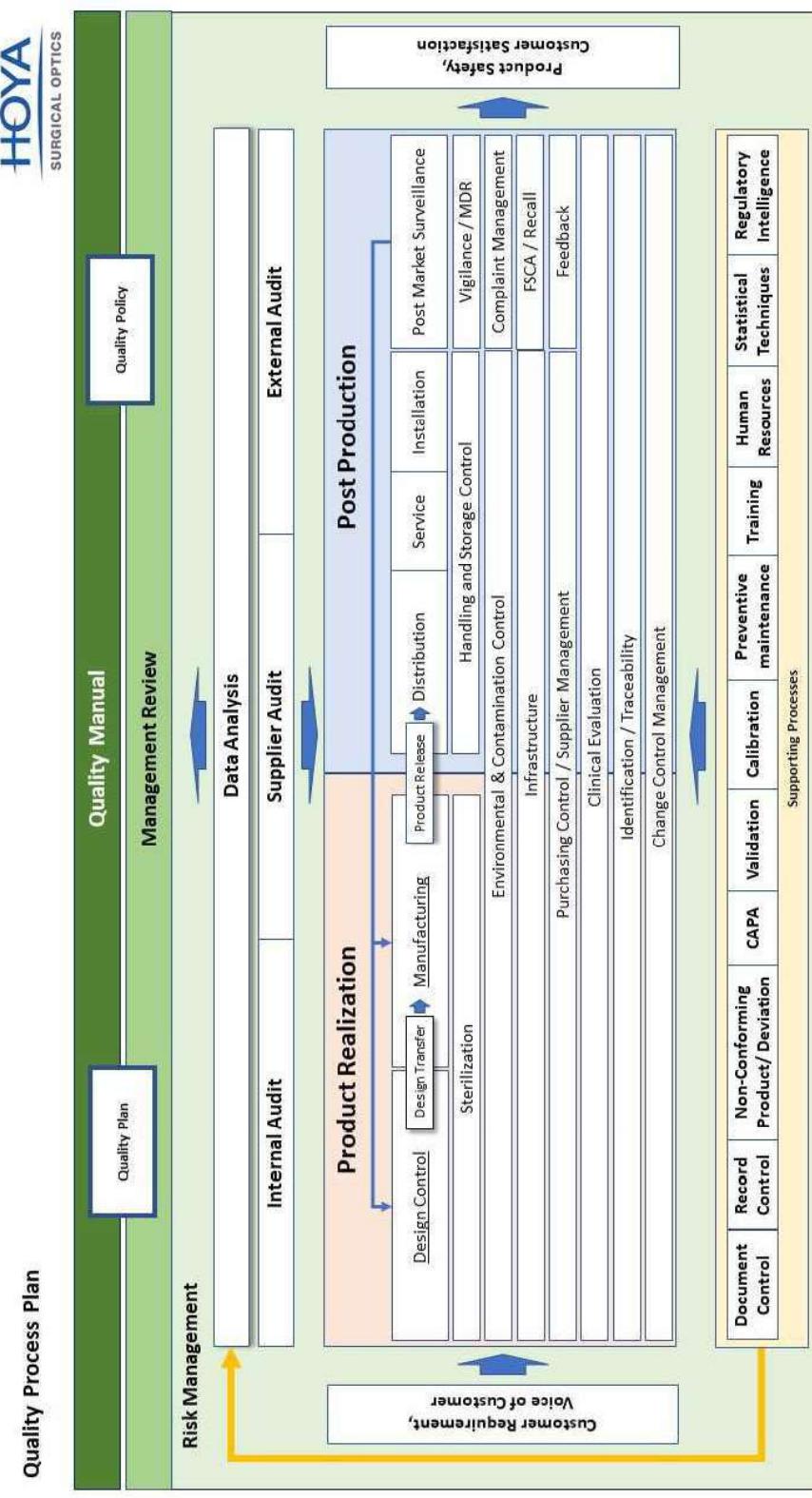


Figure 1: HSO - Quality Process Plan

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Hoya retains responsibility of the outsourced processes to ensure that the process remains in conformity with the standards and applicable regulatory requirements. Adequate controls are in place to ensure quality of outsourced process, including Quality Agreements and quality checks of the incoming material and where required supplier audits are in place.

A risk-based approach is adopted to ensure that the patient is exposed to least possible risk. All major QMS processes undergo a risk assessment to identify the potential risk and residual risk. A risk management program is in place to identify and mitigate any risk above a predetermined threshold.

Appropriate controls are in place for operation and control of these processes. All the processes are owned and manned by competent and trained personnel. Output from the process are periodically reviewed at appropriate platforms.

Any changes to the process are evaluated for their impact on the safety and efficacy on the medical device as well any regulatory implication.

All software applications that may directly or indirectly impact the quality of the products are appropriately validated prior to use in GMP environment.

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4.2. Documentation Requirements

4.2.1 General

The quality management system comprises out of the following key elements:

- Quality Policy
- Quality Manual
- Global Policies
- Documented Procedures (including associated work instructions, templates and forms)
- Records

The official language for all QMS documents and records / reports including any quality records/ report is English. Translations of English source documents are allowed, however, in case of inconsistencies between the English version and a translated version the English version prevails. It is the responsibility of local QA to ensure an adequate translation process is in place, if local language translations are needed.

4.2.2 Quality Policy

- Defines commitment to quality and maintain effectiveness of the QMS by top management
- Directs the organization to comply with requirements and to continuously improve

4.2.3 Quality Manual

- Defines the scope of the Quality Management System
- Outlines documentation related to the Standards
- Guides more detailed operating procedures, work instructions, and records which governs the interactions between the processes of the Quality Management System.

4.2.4 Global Policies

- Drives global alignment and harmonization around key interpretations of the regulations across the HSO entities. Policies serve as an input & guidance to the development of SOPs for each HSO site.

4.2.5 Documented Procedures

- Defines the processes and its implementation at Hoya to comply with the regulations and Standards
- Procedures may be supported by detailed work instructions, templates and forms to allow the employees to execute the processes.

4.2.6 Records

- Evidence of the use and effective implementation of the Documented procedures established in HSO Global Quality Management System

4.2.7 Quality Management System Structure

HSO–Global Quality Management System documentation hierarchy is structured as follows:

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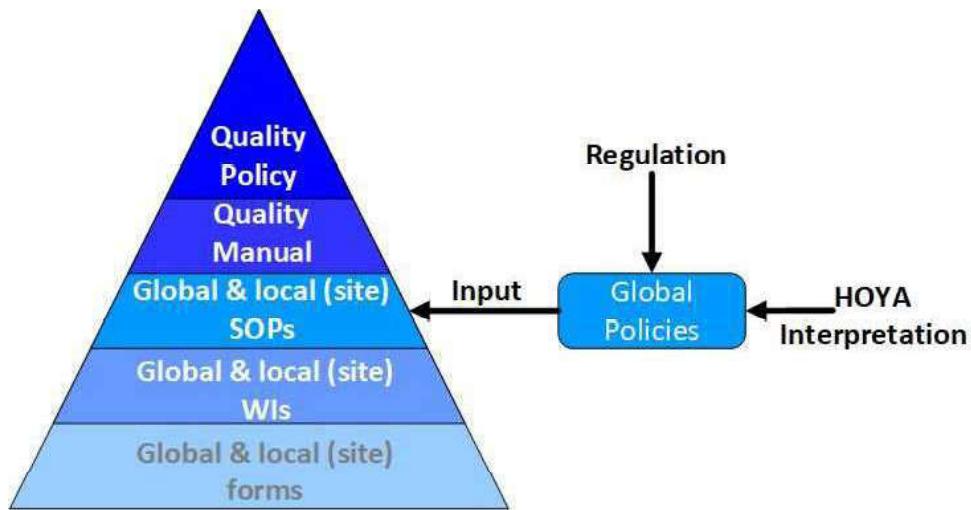


Figure 2: HSO Quality Management Structure

Global Quality Manual is applicable for all sites described in point 2.1. Global SOPs are applicable for all sites within their scope. In case local site SOPs/WI need to be created, they should be based on Global SOPs and WI, those Global SOPs/WI should be clearly identified as a “parent” document for site/local SOPs/WI. This change will be introduced as a rolling change during local SOPs/WI revision. List of All Global SOPs/WI is available in the master control as [Form_Appendix-22-001](#).

4.2.8 Medical Device Files

For each product family the QA shall maintain a list of records according to OPS-18-080 Device Master Record. The content of the device master record shall satisfy the requirement for the Medical Device Files. Product families for IOLs have been defined based on intended use, IOL material(s), IOL delivery method.

4.2.9 Control of Documents

The QA department ensures that the procedure for the control of all QMS documents that relate to the requirements of the applicable international and regulatory standards, including documents of external origin such as Standards and customer drawings, are adhered to. This includes the issuance and system maintenance of controlled documents. Controlled documents shall be available, legible, identifiable and up to date.

Document control within HSO applies to QMS documents in hardcopy as well as electronic format. Documented procedures establish the process for generating, amending, and revising controlled documents that includes, but is not limited to, the following:

- Identifying owning department, initiator, affected departments / personnel
- Identifying personnel responsible for reviewing documents for adequacy and authorization, including alternates
- Maintaining document change history

Documented procedures establish the process for the control, distribution, retrieval, removal, and retention of controlled documents that includes, but is not limited to, the following:

- Identity and control of the master copy and obsolete copy.
- Identity and distribution of controlled and uncontrolled copies.

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- Effective date upon which a document becomes valid and mandatory.
- Duration and conditions for document history, storage, and retrieval.

Unless specified differently in regulatory requirements, HSO policies, SOP's or customer requirements, quality related document retention is denoted in the Document and Records Control procedure.

Documented procedures establish the process for the periodic review confirming that controlled documents remain current and effective.

A master list of all current valid QMS documents is maintained.

Changes to documents are documented in procedures which include, but are not limited to:

- Requirements for effective and efficient control of changes.
- Requirements that changes be identified, recorded, evaluated, reviewed, and controlled to evaluate any effect on other processes.
- Authority for initiation, review, and approval of changes.

4.2.10 Control of Records

Documented procedures establish the process for protecting, identification and legibility, as well as storage, retrieval, disposition, retention, and disposal for all records whether of internal or external origin, whether hardcopy or electronic format.

Records are established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system. Quality records required by company procedures are controlled and the following requirements are defined, as applicable:

- Archiving responsibilities for each quality record
- Retention methods to prevent damage, deterioration or loss
- Retention periods, both paper and electronic
- Disposal methods
- Reproduction methods

A master list of all records shall be maintained where deemed necessary for ease of records retrieval.

HSO ensure that when records are received that contain information that is considered confidential personal health data, then this data is appropriately identified and treated and protected as per the applicable legal regulations.

Unless specified differently in regulatory requirements, Global policies, SOPs or customer requirements, quality related records retention is denoted in the Document and Records Control procedure.

5.0 MANAGEMENT RESPONSIBILITY

5.1. Management Commitment

Top management (CEO and the GMT) is committed to the development and implementation of the quality management system and maintaining its effectiveness by:

- Communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements through presentations, employee meetings and other media.
- Publishing the quality policy in prominent locations.
- Ensuring that quality objectives via Quality plan are established and communicated in measurable terms at each management level.
- Conducting management reviews, and
- Providing resources through review of workloads, quality issues and customer, statutory and regulatory requirements.

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Top management of HSO committed to implement and maintain effective risk management process throughout the life cycle of the medical device with appropriated qualified resources and periodic review of suitability and efficiency of the risk management activities and implement improvements as required.

5.2. Customer Focus

Top management ensures that customer requirements are determined and are well understood, and the customer satisfaction is systematically monitored as a measure of performance in determining and meeting customer requirements.

5.3. Quality Policy

In formulating the HSO quality policy see QM-16-001 A1, the CEO ensures that the policy is appropriate to the purpose of the company and includes a commitment to comply with the requirements and continually improve the effectiveness of the quality management system.

The Quality policy provides a framework for establishing Quality Plan which in turn develop into specific quality objectives, and provides direction for the continual improvement effort, and its role is explained and discussed at the general orientation training provided to all employees. The quality policy is also communicated to customers and other interested parties.

The Quality policy is periodically reviewed within the framework of management reviews of the quality system. This is ensuring its continual relevance and suitability.

5.4. Planning

5.4.1 Quality Objectives

Top Management i.e. CEO, Management Representative and GMT, establishes and communicates annually the quality objectives for relevant functions. Objectives are measurable and consistent with Quality Plan and Quality Policy.

5.4.2 Quality Management System Planning

Quality Planning is documented in Quality Plan which represent a long-term quality vision and is an integral part of the business process. Other strategic plan such as company strategic plans, project plans, product registration strategies, budget plans, continuous improvements and management review output are other elements of Quality Management system planning.

Quality Planning represents an inherent function in the efforts to meet the company's Quality Objectives and to ensure the integrity, continued suitability and effectiveness of the Quality Management System.

Processes are in place to ensure the integrity of the quality management system is maintained when changes are planned and implemented (e.g., Management Review, project planning, document review and approval requirements).

The output of quality system planning is documented in this quality manual, in associated operational procedures, in quality records and in other referenced documents.

5.5. Responsibility, Authority and Communication

5.5.1 Responsibility and Authority

The Human Resource (HR) department coordinates with the Heads of Department (HOD) or functional managers to ensure that the responsibility, authority and interrelation of all personnel who manage, perform and verify work affecting quality are defined and documented in the Organization Charts, and in Job Descriptions.

QA department coordinates with the Heads of Department (HOD) or functional managers to ensure that the responsibility, authority and interrelation of all personnel who manage, perform and verify work affecting quality are defined and documented in company SOPs, WIs and/ or other support documents.

All employees (include temporary and contract) have a job description and a copy of the job description are kept by HR in the employee personal file. The job description will include the following information at a minimum:

- Job Title
- Department

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- Main Purpose of Job
- Key Duties & Responsibilities
- Authority
- Essential Experience/Skills

The immediate supervisors are responsible for defining the job descriptions for their employees. The job descriptions are approved by the HOD or functional manager and reviewed by HR. The employees are briefed about the content of the job descriptions and confirm the acceptance of these responsibilities and authorities. Deputies for key personnel shall be nominated. These deputies are nominated on the basis of their capabilities to assume the responsibilities of the principal personnel when necessary. The supervisor of a person is authorized to be the deputy of this person unless otherwise documented. The responsibility and authority is communicated within the organization to enable all employees to contribute to the achievement of the quality objectives.

5.5.2 Management Representative

The Head of Global QA is assigned by the CEO to be the Global Management Representative, who holds the authority and responsibilities for:

- Ensuring Regional / Site Management Representatives are allocated to the individual regions / sites where HSO conducts its businesses.
- Ensuring that product meets specified requirements.
- Ensuring Regulatory Compliance, including fulfilling the responsibilities laid out in article 15 of the European Medical Device Regulation (Person responsible for regulatory compliance).
- Ensuring that the requirements such as listed in paragraph 2.2 and the company's documented Quality Management System are implemented and maintained.
- Ensuring the performance and effectiveness of the Quality Management System are reported to top management for review and as a basis for improvement.
- Ensuring the promotion of awareness of regulatory and customer requirements throughout the company.
- Liaising with external parties on matters relating to the quality management system and regulatory compliance.

5.5.3 Internal Communication

Internal communication regarding the quality system flows two ways:

- Top management communicates to the organization the quality plan and objectives; customer and regulatory requirements, product and process specifications; verification and validation requirements, and instructions on how to implement and use the quality system.
- The organization communicates to management information and data regarding quality performances, the effectiveness of the quality system, customer satisfaction, and opportunities for improvement.

The information is communicated through:

- Paper or electronic documents, such as manuals, procedures, instructions, drawings, specifications, quality records, reports, etc.;
- Emails, memos, meetings and/or intranet;
- Training and awareness programs; and
- Employee suggestions, surveys and feedback.

Management review meetings have a special role in ensuring proper communication between the top management and the organization. The meeting provides the framework for the organization to report on the status of quality-related issues and activities to change and/or improve the quality system.

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The QA Department has the overall responsibility for ensuring that all pertinent documents, reports and records are distributed to appropriate departments and functions, and that information and data about quality performance and the effectiveness of the quality system are reported to the Top Management.

5.5.4. External communications

Hoya established effective process for the communication with the Competent authorities, notified bodies, customers and other economic operators. Those communications are captured and described in specific processes related procedures.

Hoya is maintaining an effective organizational structure with appropriate resources to ensure that required communication occurs internally and externally concerning the importance of meeting customer, statutory and regulatory requirements.

Examples of communication include but not limited to:

- Communication with the Competent Authorities. The key processes for communication with the Competent Authorities worldwide (not limited to) are market approvals and change notifications (where applicable), Field Safety Corrective Actions and PMS/Vigilance processes.

HSO maintains procedures for generating, authorizing, and issuing Field safety corrective actions (advisory notice, recalls, market withdrawals), when it is determined to be necessary for each Competent Authority and provide appropriate communication as required.

Hoya notifies the appropriate Competent authorities of reportable device incidents (vigilance cases/AE) related to HSO products, that Hoya has become aware of according to applicable regulations and timelines.

In addition, HSO can receive any request from the CA/NB regarding product/market/certification related information and shall address them in a timely manner.

- Communication with Notified Bodies. This communication is specific to the EU Union. In accordance with MDD/EU MDR communication with NB occurs for Products certification (CE marking), QMS ISO/MDSAP certifications, notification about significant (substantial) changes, PMS processes (FSCA and device vigilance, trending etc).
- Communication with Customers. Communication with customers occurs regarding information related to product, storage and transport conditions, regulatory requirements (e.g. EU MDR), customers complaints, the terms and conditions of sale, Quality agreements and contracts, etc.
- Communication with other external interested parties/Economic Operators. Other external communication can occur with research centers, healthcare professionals, scientific institutes, company's Suppliers and Service providers, EU AR, Importers.

5.6. Management Review

5.6.1 General

Top Management reviews the quality management system periodically, preferably bi-annually, but at least once each Financial year. Such reviews assess the suitability, adequacy, and effectiveness of the quality management system, which in turn will become input for quality management system improvement. Records of management reviews are documented and maintained.

5.6.2 Management Review Input

The following elements are considered during the management review meeting at the least.

- Customer Feedback
- Complaint handling
- Reporting to regulatory authority
- Audits
- Monitoring and Measurement of processes
- Monitoring and measurement of products
- Corrective actions

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- Preventive actions
- Risk Management
- Follow-up actions from previous management review
- Changes that could affect the quality management system
- Recommendations for improvements
- Resources
- Applicable new or revised regulatory requirement

The procedure enables the agenda a certain degree of flexibility in addressing additional significant issues as required.

5.6.3 Management Review Output

A procedure establishes that decisions reached, and actions assignments and completions be documented that address but are not limited to the:

- Improvement of the effectiveness of the quality management system and its processes,
- Continuous improvement of product related to customer requirements, and
- Changes needed to respond to applicable new or revised regulatory requirements
- Resource requirements

Management review output items are documented, disseminated the information to item owners, tracked and monitored by quality function. Records are maintained by the Quality Department.

6.0 RESOURCE MANAGEMENT

6.1 Provision of Resources

Management with Executive Responsibility identifies and provides adequate resources needed to perform the following:

- Implement the quality policy and continuously improve its effectiveness.
- Satisfy customer and regulatory requirements.

Depending on the type of nature of operation or activity, resource requirements are defined in:

- Quality manual, operational procedures and work instructions.
- Product and process drawings and specifications, records management and data storage.
- Production plans.
- Personnel requirements, job descriptions, competence matrices, and training programs.
- Supplier and Distribution agreements and contracts.
- Facility plans, business software applications and data processing equipment plans.
- Minutes of management reviews, quality objective records, and corrective and preventive actions.

6.2 Human Resources

6.2.1 General

The requirements considered during the identification and allocation process for human resource include the assignment of qualified personnel based on education, training, skills and experience, for the management and performance of work affecting product quality.

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6.2.2 Competence, Awareness and Training

HSO has established a job description for all roles. Competency of the prospective candidate is established based on educational qualification and experience and expertise to perform the task defined in the job description. Various techniques like skill assessment, document review and personal interview are employed to judge the competency of the individual to perform the tasks assigned in the job description.

All new employees (including temporary employee) will be provided with Induction / onboarding training to familiarize them with the company policies and are trained by qualified personnel according to the activity they are performing. Job Competency training is provided by hiring manager and may take the form of “on-the-job” training / self-read / formal seminars / workshops outside of the immediate work environment.

The HR department establish and maintains a procedure for the identification of training needs including on-boarding and to coordinate training of all personnel performing activities directly affecting quality. HR department collaborates with the respective HODs for identification of training needs.

Note: In some Hoya entities, Site QA is responsible for identification of training needs (and assignment of required training in the Quality Management System, MasterControl) and HR responsible for on-boarding only. Based on the training needs, a training plan is put together to ensure relevant programs are organized to equip all employees with the appropriate skills for performing their assigned tasks.

Training for the appropriate personnel also includes awareness of device defects which may occur from the improper performance of specific tasks. Personnel who perform verification and validation are also made aware of the defects and errors that may be encountered as part of their job functions.

6.2.3 Training Effectiveness

Training effectiveness is determined and monitored through a variety of processes, including direct and indirect measures:

- Indirect measures, such as internal and external audit results, are subject to Management Review with emphasis on audit findings that may point to training related issues.
- Direct measures, such as quality metrics, job performance indicators by measuring job errors, productivity rates, or similar indicators that reflect an employee's effectiveness. Further, during or following training sessions, quizzes or questionnaires may be used to determine the effectiveness of the training conducted.

Feedbacks are provided to employees during the performance review to make sure the employees are aware of the relevance and importance of their activities and how they have contributed to achieve the quality objective. Quality objective by default are embedded into personal objectives of the employees.

The HR department ensures that appropriate records of education, skills and experience are maintained. Quality Assurance department ensure appropriate training records of all personnel are maintained either electronic or on paper. Training records are filed and maintained for individual employees. These documents may include individual or group training records, professional certifications, education and experience transcripts.

Temporary personnel are trained or work under the supervision of a trained person. Consultants advising on quality matters provide credentials and records of their suitability and qualifications that are maintained along with a record of the type of services provided.

6.3. Infrastructure

Management with Executive Responsibility shall comply with requirements and standards from governmental and other agencies and, as appropriate, customers. The design and flow of the material ensures that product quality and integrity is maintained throughout the process. Such compliance will determine, provide, and maintain the necessary infrastructure that includes but is not limited to the following:

- Buildings, workspace, and associated utilities
- Related hardware and software,
- Supporting services

A documented procedure establishes the process and requirements for maintenance activities and records, where applicable.

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6.4. Work Environment and Contamination Control

HSO ensures that the work environment at the various relevant facilities is appropriately managed to achieve conformity to product requirements.

Therefore, HSO ensures the relevant facilities meet the following requirements:

- Having documented requirements for health, cleanliness and clothing of personnel if contact between such personnel and the product or work environment could adversely affect the quality of the product.
- If work environment conditions can have an adverse effect on product quality, the establishment of documented requirements for the work environment conditions and documented procedures or work instructions to monitor and control these work environment conditions.
- Requirement that all personnel who are required to work temporarily under special environment conditions within the work environment are appropriately trained or supervised by a trained person.
- As appropriate, establishment of special, documented arrangements for the control of contaminated or potentially contaminated product in order to prevent contamination of other product, the work environment or personnel.
- HSO has specified requirements for control of contamination with microorganisms or particulates and maintained the required environmental cleanliness during critical stages of the manufacturing process like final inspection and primary packaging.

6.5. Maintenance Activities

HSO ensures that the maintenance activities at various facilities are appropriately managed to achieve conformity to product requirements.

Therefore, HSO ensures that the relevant facilities meet the following requirements:

- Having documented procedures with requirements for maintenance activities for production processes, systems, and equipment that may affect product quality. Records shall be maintained for these activities.
- Having procedures for the management, cleaning, and maintenance of the physical premises in accordance with applicable regulations so as to avoid product contamination.
- Establishment of sufficient controls on computerized systems for installation, operation, maintenance, modification, and security. These systems shall be evaluated for potential validation.
- Having and maintaining appropriate supporting technical documentation for all critical equipment and installations used for the production, storage and distribution of HOYA products.

7.0 PRODUCT REALIZATION

7.1. Planning of Product Realization

7.1.1 Product and quality planning

R&D plans the design verification and validations to meet the customer requirements and ensure other processes of the Quality Management systems are integrated as needed during the design and development of the products. R&D and Global Operations plan production processes and product verification activities; the planning includes the determination of:

- Requirements and quality objectives for products and processes;
- Development of production processes; establishment of process specifications, operator instructions and other such documentation; and identification of training requirements for process operators;
- Identification of required product verification, inspection, test and monitoring activities, and the criteria for product acceptance and release; and
- Documented evidence of product and process conformity with specified requirements is documented in the Device Master Record (DMR)

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Results of production and inspection, test and monitoring activities, and the criteria for product acceptance are documented in the Lot Traveler or Device History Record (DHR).

7.1.2 Risk Management

Risk Management activities and Quality Planning are an integral part of HSO Global Quality Management System.

The risk management activities is supported by adequate resources and assignment of qualified personnel at each level of the organization as appropriate.

R&D / Global Operations/QA employs formal Risk Assessment / FMEA processes for all main processes, material changes or introduction of new materials into the operations and products as deemed appropriate by management or specified within their SOP's.

This assessment includes the identification of hazards that are associated with the product, the estimation and evaluation of the risks associated with each hazardous situation, as far as possible reduction of individual and residual risk, control of those risks and monitoring the effectiveness of those controls.

Risk analysis studies may also be conducted for key manufacturing and other product realization processes. This is to identify high-risk activities and to focus the quality system controls on these areas, and thus reduce the risk.

Risk management files are maintained per product family and periodically reviewed.

Risk-based decisions occur throughout the quality management system processes including but not limited to CAPA, change control, field actions and complaints management.

7.2. Customer-related Processes

7.2.1 Determination of requirements related to the product

HSO regional entities are responsible for contract reviews that determine requirements specified by the customer, including requirements for delivery and post-delivery activities (include conducting customer communications);

The R&D HOD and Global Marketing HOD are responsible for determining requirements that are necessary for specified or intended use of a new or modified product.

The appropriate RA department reviews any proposed new and revised contracts for the distributors, changes to registrations, labeling, Design, manufacturing processes that effects customer safety. RA department also ensures all country specific regulatory requirements are met and in compliance to HOYA Quality Systems.

The appropriate QA department reviews any proposed new and revised contracts for suppliers, distributors, manufacturing process changes, Design changes, product storage and Distribution.QA department also responsible for post market Quality activities such as complaints, adverse event reporting processes, data trending for potential improvements to product and processes. QA department also ensures all aspects of the company's quality management system are met and in compliance with country specific regulatory requirements.

Note: The primary responsibility for adverse event reporting is laying within Global QA organization. Based on presence in the country this responsibility may change between QA / RA departments at HSO dependent on the country.

7.2.2 Review of requirements related to the product

The HSO regional entity shall before acceptance of a contract or purchase order, the contract or purchase order is reviewed to ensure:

- The requirements are adequately defined and documented; where no written statement of requirement is available for an order received by verbal means, the outsourced distributor is to ensure that the order requirements are agreed before the order is accepted.
- Any differences between the contract or order requirements are resolved.
- The HSO regional entity has the capability to meet the contract or order requirements.

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- Applicable regulatory requirements are met
- Results of such review are recorded and maintained.

The contract can be amended based on mutual agreement with the customer. The changes are documented by the HSO regional entity Quality Department and then communicated to the functions concerned within the organization. The changes are recorded and maintained.

7.2.3 Customer Communication

The process for communicating effectively with customers is defined to ensure adequate understanding of the needs and expectations. This includes communicating with customers in relation to;

- Product Information
- Enquires, contracts or order handling, including amendments
- Customer feedback, including complaints, and
- Reporting of complaints to regulatory authorities e.g. Medical Device Reporting (MDR), medical device vigilance and Advisory Notices
- Reporting of safety related information through Field Safety Corrective Actions/ Advisory Notices.

7.3. Design and Development

Note: Design and Development is not applicable for HSO regional entities (HSOE, HSOU & Distribution sites)

7.3.1 Roles and Responsibilities

Pipeline Governance Committee (PGC) was established by GMT to ensure design and development activities are performed in accordance with business needs and in compliance with regulatory requirements.

PGC and the assigned Project Director (as appointed by VP R&D) are responsible for ensuring that any product design, development and design change activities are managed in a systematic manner and in accordance with documented procedures.

This includes:

- Regular review of the design and/or project plans to ensure sufficient resources are allocated and
- Any issues arising from the projects are appropriately resolved.
- Approval of changes in design input

During those reviews HOD Global Quality or the assigned Quality representative participate in the role of independent reviewer.

The R&D project teams are responsible to ensure that the specified requirements for the product design are met and that the design activities are carried out in accordance with documented procedures.

7.3.2 Design and Development Planning

The R&D HOD ensures that each design and development activity is planned by assigning the project to the relevant R&D Project Director.

The R&D Project Director assembles a team consisting of qualified persons from the different functional groups, which forms the basic interface structure for the project, prior to the initiation of the project. All the relevant information resulting from these interfaces are documented as part of the project deliverables for various project phases.

The R&D Project Director ensures that plans describe or reference all related activities and define responsibility for their implementation. The team must ensure that plans are updated as the design evolves and that all design activities are carried out in accordance to the documented procedures.

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7.3.3 Design and Development Inputs

As part of the project phase deliverables, all input requirements relating to the product, including the requirements that are related to the safety of the medical device, applicable statutory and regulatory requirements are identified and documented.

The R&D Project Director reviews the identified design input requirements for adequacy, taking into consideration the results of any contract review activities pertaining to the project; incomplete, ambiguous or conflicting requirements must be resolved with the relevant parties and the resolution documented Design History File.

Design input requirements are documented and approved by the relevant functional managers.

7.3.4 Design and Development Outputs

The R&D Project Director documents design output as part of the Design History File (DHF) in terms that can be verified and validated against design input requirements.

This design output will meet the design input requirements and contains or makes reference to acceptance criteria; in addition, the design output identifies those characteristics of the design that are crucial to the safe and proper functioning of the product e.g. operating, storage, handling, maintenance and disposal requirements.

The R&D Project Director conducts a review of the design output against design input prior to the release of the design output document and confirms that design output is complete before recommending for the project to move to a next design phase.

7.3.5 Design and Development Review

At appropriate stages of the project, the R&D Project Director plans and conducts formal design reviews with R&D project team as mentioned in 7.3.1.

The R&D Project Director ensures that the design reviews are conducted with the participation from the team members, key members of the Top Management as well as independent specialists as and when required at the different phases of design and development. During design review the HOD Global Quality or the assigned representative acts in the role as independent reviewer.

The R&D Project Director also ensures that the result of the review is documented and maintained as a quality record in the Design History File.

7.3.6 Design and Development Verification

As appropriate, the R&D project team defines what design verification activities may need to be performed to ensure the design output meets the design input requirements.

Design verification activities are performed and documented by the process development team within Global Operations in verification plans and / or work instructions that include methods, acceptance criteria, and as appropriate statistical techniques with rationale for sample size.

Results and conclusions of design verification activities are recorded and maintained as quality record as part of the Design History File.

These design verifications may include activities such as performing alternative calculations, comparing the new design with a similar proven design, undertaking tests and demonstrations, and reviewing the design stage documents before release.

7.3.7 Design and Development Validation

As appropriate, the R&D project team defines what design validation activities may need to be performed to ensure the product is capable of meeting the requirements for the specified application or intended use.

Design validation activities are performed and documented by the process development team of Global Operations in validation plans and / or work instructions that include methods, acceptance criteria, and as appropriate statistical techniques with rationale for sample size.

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Design validation is conducted with representative product; the rationale for selection of the products for design validation is documented.

As part of design validation, a clinical evaluation is performed per applicable regulatory requirements.

In case the clinical evaluation indicates that a clinical investigation must be performed to validate product performance and/or safety, the clinical investigation must be prepared and executed per documented requirements and meet all applicable regulatory requirements for the conduct of clinical investigations.

Results and conclusions of design validation activities are recorded and maintained as quality record as part of the Design History File.

7.3.8 Design and Development Transfer

Procedures for transfer of design and development outputs are documented.

Design and development outputs are verified as suitable for manufacturing before final production specifications are approved.

As part of Design Transfer, it is confirmed that production capability can meet the product requirements.

Results and conclusions of the design and development transfer are documented and filed as part of the Design History File.

Responsibility for maintenance and compliance of the product and process design is transferred from R&D to Global Operations at completion of Design Transfer.

7.3.9 Control of Design and Development Changes

The responsibility for controlling design and development changes depends on the phase in the lifecycle of the product:

- Prior to completion of Design Transfer Review DT1 the R&D Project Director is responsible for managing and documenting changes implemented during design control execution.
- After completion of Design Transfer Review DT2 Global Operations is responsible for managing, documenting, and implementing changes in product and/or process design.

Documented procedures are in place to control design and development changes. Changes are reviewed for significance of the change to the function, performance, usability, safety and applicable regulatory requirements.

All changes that may impact product quality or compliance are reviewed, verified, validated as appropriate, and approved before implementation.

The QA department is responsible to verify that R&D and/ or Global Operations ensures that all proposed changes to existing product, process or labelling are reviewed per documented procedure; this includes requirements for:

- Review and approval of changes prior to implementation by relevant functions.
- Assessment of any change to design and development as to the effect of the change on constituent parts and/or product already delivered.
- For any changes that may significantly affect products supplied:
 - Notification of the customer and any applicable regulatory agencies, as appropriate.
 - Review of existing validation and support documents to revise as required and conduct retraining where appropriate.
 - Evaluation of products and process changes for risk and mitigation strategy to reduce the risk.

7.3.10 Design and Development Files

For each product family a Design History File is maintained.

Product families for IOLs have been defined based on intended use, IOL material(s), IOL delivery method.

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Design History Files include or reference records that demonstrate conformity to the requirements for design and development and include or refer to records for design and development changes.

7.4. Purchasing

7.4.1 Purchasing process

Documented procedures are established to ensure purchased product, components, and services meet specified purchasing information.

Materials and components used in medical devices intended for use in clinical investigations or commercial distribution, and finished medical devices sourced from suppliers must be purchased from approved suppliers.

Suppliers are evaluated, selected, and QA-approved per documented criteria for selection, evaluation, monitoring and re-evaluation; these criteria cover, but are not limited to:

- Ability to provide product or service that meets the purchasing information
- Performance of the supplier
- Impact of the product or service on the quality of the medical device.

Records of the results of supplier evaluations and any necessary actions arising from the evaluation are maintained. These quality records include, but are not limited to:

- Approved supplier list (ASL)
- Supplier Audit Reports
- Supplier Agreements
- Quality Improvement Plan
- Purchasing Documents

Non-fulfillment of purchasing requirements shall be addressed with the supplier. Disposition of such material are decided by Material Review Board based on the associated risk.

7.4.2 Purchasing information

For each product or service that may impact the quality of the medical device relevant purchasing information is documented, and contains, but is not limited to:

- Requirements for approval or qualification of product, procedures, processes and equipment.
- Requirements for personnel qualification.
- Quality management system requirements. Requirements for notification of changes in specifications, processes and/or suppliers used to provide the purchased product or service.
- Maintenance of relevant purchasing documents and records required for traceability.
- Confirmation of adequacy of specified purchase requirements prior to their communication to the supplier.
- A written agreement that requires suppliers notify the organization of changes in the purchased product prior to implementation of any major changes that may affect the product quality or specification.

7.4.3 Verification of purchased product

Documented procedures are established to ensure that purchased product is verified at receipt for conformance with specified requirements before use; the procedures are risk based and include, but are not limited to:

- Process Control Plans (PCP)
- Required verification, inspection, and other receiving activities

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- Requirements for quarantine, approval, and release of incoming materials.
- Requirements for recording results of receiving activities
- A description of the sampling method
- Description or reference to procedures, facilities, and equipment to use designed to avoid contaminants

In case verification of purchased product needs to happen at Subcontractor's Premises The following requirements need to be met:

- Purchase Order must include at the minimum the requirements for verification arrangements, and the method of product release
- Purchase Order must include all contractual requirements agreed with the supplier, including the right to verify at the subcontractor's premises that subcontracted product conforms to specified requirements.
- Records of the verification must be maintained.

In case during verification activities any non-conformance and/or changes in the purchased product are observed, the purchased product must be quarantined to assess the impact on the medical device for which it is used. As decided by the Quality, a Supplier Corrective Action Report (SCAR) is initiated to ensure supplier continuously meets the requirements of HSO.

7.5. Production and Service Provision

7.5.1 Control of production and service provision

Global Operations is responsible to ensure all process control parameters complies with specified requirements, and the relevant regulatory requirements as listed in section 2.2.

The QA department is responsible for ensuring specified requirements are documented and communicated to Global Operations, and to verify that production activities are carried out under controlled conditions, covering:

- The availability of information that describes the characteristics of the product.
- The availability of documented procedures, documented requirements, work instructions, and reference materials and reference measurement procedures as necessary.
- The adequate installation and use of suitable equipment.
- The training and controls on personnel effect on quality
- The effectiveness of environmental controls
- The availability and use of monitoring and measuring devices.
- The implementation of monitoring and measurement procedures.
- The implementation of release, delivery and post-delivery activities.
- The implementation of defined operations for labelling packaging.

This is accomplished through review of regular monitoring reports provided by Global Operations as well as through regular internal audits.

Each batch of finished products has a Device History Record that contains at the minimum:

- Quantity manufactured and quantity approved for distribution
- Results or reference to results of quality inspections
- Sterilization records, if applicable
- Information to allow traceability to the level required by applicable regulation.

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Device History Records are verified and approved by the authorized quality personnel as part of product release for distribution.

Any changes to the process control parameters that affect the specified requirements, or the quality of the finished products are reviewed and approved by QA department.

The label specification or artwork established must be approved at the minimum by RA/ QA department and only issued to Global Operations for printing in controlled areas.

7.5.2 Cleanliness of product and contamination control

Procedures are established to ensure that the production environment and the product meets the level of cleanliness required to ensure that sterility can be achieved when product is exposed to the validated sterilization process.

The QA department verify that established documented requirements for cleanliness of product and product environment are adequate.

Manufacturing facilities are regularly monitored to ensure the specified requirements are met as required. The effectiveness of the environmental monitoring is verified through regular audits of the manufacturing facilities.

7.5.3 Installation activities (Applicable for RUCK, HSOE and HMIN only)

Procedures are established to ensure installation activities are performed in controlled manner to ensure quality of the finished products are met. Installation records (not limited to service report and checklist) are to be kept as part of quality records.

The QA department verify the established documented requirement for installation activities are adequate.

7.5.4 Servicing Activities (Applicable for RUCK, HSOE and HMIN only)

Procedures are established to ensure servicing activities are performed in controlled manner to ensure quality of the finished products are met. Servicing records (not limited to service report and checklist) are to be kept as part of quality records.

The QA department verify the established documented requirement for installation activities are adequate.

7.5.5 Particular Requirement for sterile medical devices

The Sterilization process shall be performed within one of the factories or at a location of an approved supplier.

Sterilization facilities shall maintain records of the validated process parameters for each batch of products sterilized.

Copies of the sterilization records are traceable to each batch of products manufactured and are kept as part of the Device History Record.

7.5.6 Validation of processes for production and service provision

The responsible process or application owner will validate the following processes/applications per documented procedure to ensure that the planned results can be achieved consistently:

- Special processes for which results cannot be fully verified by subsequent monitoring or measurement,
- Quality critical processes as defined per risk management process
- Software applications used in production and service provision

The extent of validation work required depends on the risk of the process/application for the quality of the finished product.

Validation procedures include, but are not limited to the following;

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- Defined criteria and approval procedure, identifying the quality critical attributes of the process.
- Equipment qualification/validation and/or verification requirements.
- Qualification of personnel for processes/task requiring special skills
- Software and associated electronic records validation requirements.
- Activities that provide documented evidence of development, maintenance, change control, and support of systems
- Review and approval of documented evidence and record retention
- Revalidation/re-verification as required
- Requirements for archiving and maintenance of records and associated actions

7.5.7 Requirements for validation of processes for sterilization & sterile barrier systems

The sterilization process and sterile barrier systems are validated per documented procedure to ensure compliance to specified requirements prior to initial use; in addition, the sterilization process is periodically revalidated.

The sterilization (re)validation is performed in accordance with a written protocol initiated by the sterilization facility with approval from the QA department prior to execution.

Records of validation of each sterilization process and sterile barrier system are maintained.

7.5.8 Identification

HSO has procedures established and implemented for appropriate identification throughout product realization and distribution for all finished products, and their sub-components where applicable.

Where required by applicable regulations finished products do include a suitable UDI (Unique Device Identifier).

Any finished products that are returned to Global Operations for reprocessing to specified requirements are clearly identified and segregated from the products approved for sales and distribution.

The QA Department verifies that Global Operations follows the requirements with respect to identification as follows, but not limited to:

- Allocation sufficient, appropriate storage locations to meet the established procedures on segregation of conforming from non-conforming and returned product, and from products on hold or in quarantine.
- Product status is indicated with marking and/or location, either physically or by electronic means with respect to inspection, test, acceptance, concession, hold, rejection, rework, disposal and/or clearly identified and segregated from the products approved for sales and distribution
- Product status identification labeling is maintained and applied through the entire manufacturing process.
- Processes for identification are defined in documented procedures.

7.5.9 Traceability

General Requirements

- Procedures are established to ensure traceability from materials, components and subassemblies to the end-user.

Particular requirements for implantable medical devices

- For the purpose of traceability, the Device History Records have information on materials, components, subassemblies and finished products history, as well as information on where the product was shipped to. These records are maintained by Global Operations.

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- The inter-company distribution uses the established procedures to maintain adequate distribution records of finished products making reference to the consignee, quantity shipped, and Serial Number or Lot Number used. Subcontracted designated distributors/ warehouse logistic center are per Quality Agreement responsible for the maintenance of adequate distribution records of finished products making reference to the consignee, quantity shipped, and Serial Number or Lot Number used.

7.5.10 Customer Property

This clause is not applicable to the HSO quality management system as there are no customer properties provided to the company.

7.5.11 Preservation of product

The products manufactured are preserved to assure conformity of the products throughout manufacturing and delivery process. This includes ensuring the products are identified, handled, packed, stored and protected per the requirements specified in the specifications as summarized below.

General Requirements

HSO has procedures established and implemented for preserving the conformity of product to requirements during processing, storage, handling, and distribution.

The QA department verifies that Global Operations ensures that:

- The materials are handled, stored and preserved to prevent damage and they are responsible to ensure freight forwarders deliver products to customers as per specification documented in the contractual arrangement.
- The packaging configuration and processes conform to specified requirements to ensure its integrity.

Preservation

- Preservation in the form of maintaining the storage conditions is applied to products, materials, components and sub-assemblies to ensure product functionality, efficacy and safety throughout the expected shelf-life of the product is maintained.

Packaging

- Product packaging are developed and configured so as to maintain product requirement and functionality throughout manufacturing, delivery and storage for the expected life of the product.
- For sterile products, the packaging configuration used for the packaging of sterile products is validated to ensure packaging integrity is maintained throughout the customary handling, storage and delivery process. The validated packaging configuration also ensures the product requirements and functionality are maintained for the expected life of the product.

Handling and Storage

- Products are stored off the floor on pallets, racks, or shelves, so as to prevent contamination and damage, until shipment to the next consignee.
- Pallets, racks and shelves and storage environment are maintained to preserve products and to avoid damage to containers, contamination or damage of materials.
- Products are identified by Product Code, Serial Number, Lot Number, quantity, and inspection status.
- Where special environmental conditions are required, environmental conditions are monitored, and records of those conditions are kept.

Delivery

- Products are shipped using qualified suppliers.
- Where special environmental shipping conditions are required to maintain product conformity during shipping, those environmental conditions are monitored, and records of those conditions are kept.

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- Records of traceability of shipped products are maintained.

7.6. Control of Monitoring and Measuring Devices

7.6.1 General Requirements

HSO has procedures established and implemented to determine which monitoring and measurement activities need to be performed to provide evidence of conformity of the products with the requirements.

In addition, procedures are established and implemented to ensure that monitoring and measurement devices are capable to provide valid results in a manner that is consistent with the monitoring and measuring requirements.

The owner of the inspection, test, monitoring and measuring devices and equipment is responsible that the requirements for those devices and equipment are met.

The QA department verifies that the organization that follows the established procedures and that the requirements for monitoring and measuring devices and software are being met.

7.6.2 Requirements for monitoring and measuring devices and software

Monitoring and measuring devices that are used to verify the quality of products must be identified, have a visible calibration status, be in current calibration, and maintained in good condition.

Records of monitoring and measuring devices must be kept with details of equipment type, identification number, location, calibration frequency, calibration status, calibration instruction, acceptance criteria and action plans when results are unsatisfactory.

The measurement uncertainty of the monitoring and measuring devices and software must be known and be consistent with required measurement capability.

Specific requirements for software used for monitoring and measuring

- Software used for monitoring and measuring to verify the quality of products must be validated prior to use in accordance with documented procedures, and after changes so such software.
- Software validation and revalidation methods must be proportionate to the risk associated with the use of the software, and the impact on product conformity.
- Records of software validation and revalidation must be maintained.

7.6.3 Requirements for calibration and maintenance

Inspection, test, monitoring and measuring devices and equipment must be calibrated to traceable standards of known accuracy. Where no such standards exist, the basis used for calibration must be documented.

Appropriate environmental conditions must be provided for storage and handling of equipment and standards involved in calibration.

The current calibration status of inspection, test, monitoring and measuring devices and equipment must be visible on or near the device or equipment to allow users to verify the calibration status.

If equipment is ‘out-of-specification’ or there is doubt as to its reliability, it must be identified as unusable. In addition, the risk of product measurement is assessed, and necessary corrective action taken.

Inspection, test, monitoring and measuring devices and equipment does not require calibration must be identified as such on the device/equipment, and the justification must be documented in the associated device/equipment record.

Calibration, verification and maintenance of inspection, test, monitoring and measuring devices and equipment must be performed in accordance with documented procedures.

Records of calibration and maintenance must be maintained.

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8.0 MEASUREMENT, ANALYSIS AND IMPROVEMENT

8.1. General

The Top Management is responsible for establishing a methodology and system to monitor, measure, analyze and improve conformity of products, processes, and the effectiveness of the quality management system in each region / site of HSO.

Regional / Site Management is responsible for establishing a methodology and system to monitor, measure, analyze and improve conformity of products, processes, and the effectiveness of the quality management system at the region/ site.

8.2. Monitoring and Measurement

8.2.1 Feedback

QA department has established a process to gather and monitor relevant information from product realization and post-production phase to assess whether customer requirements are met. Such information includes but is not limited to type and frequency of CAPAs and non-conformances, production yields, vigilance/MDR reports, complaint category trends and levels, Post-Market Clinical Follow-up data, and general customer feedback.

Feedback information is presented as part of management review to identify areas of product or process improvement, as well as input for periodic risk management review.

8.2.2 Complaint Handling

Documented procedures are established that define requirements and responsibilities to ensure timely complaint handling, which includes:

- Complaint evaluation and documentation
- Complaint investigation
- Reportability evaluation per applicable regulations
- Returned product handling
- Evaluation whether to initiate corrections or corrective actions
- Maintenance of records
- Complaint trending

If any customer complaint is not investigated, the reason shall be recorded; the following complaints are always investigated to determine root cause:

- Possible failure modes that are not identified in the risk management file
- Labeling, or packaging that does not seem to meet any of its specification
- Events that must be reported to regulatory authorities

The results of the investigations are accessible along with identified corrective actions to all sites effected.

A complaint related CAPA is initiated for confirmed device related adverse events, as well as for situations where the action limit for the 12 months' average complaint category rate is exceeded.

If any customer complaint is not followed by corrective and/or preventive action, the reason shall be recorded.

8.2.3 Reporting to regulatory authorities

Documented procedures are established to inform appropriate regulatory authorities on complaints and adverse events that meet criteria for notification per applicable regulations, and for the issuance of advisory

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notices. Records of notifications to regulatory authorities are maintained.

8.2.4 Internal Audit

The QA department has established and manages an internal quality audit program, that ensure that periodically, the quality management systems is audited to verify that:

- Planned and documented arrangements required by ISO 13485, QMS requirements established by Hoya, and applicable regulatory requirements are met
- the Quality Management System is effectively implemented and maintained.
- all prior raised non-conformances are effectively resolved.

Internal quality audits are scheduled on the basis of the status and importance of the activity to be audited and are carried out by trained personnel independent of those having direct responsibility for the activity being audited.

The results of the audits are documented and brought to the attention of the personnel having responsibility in the area audited. In the event of non-conformances raised during the audit, the personnel responsible for the area must take timely corrective action without undue delay to eliminate detected nonconformities and their causes.

The effectiveness of implementation of corrective actions on observed non-conformances is verified during the next periodic internal audit, or in a dedicated follow-up audit, depending on the severity of the non-conformances found.

8.2.5 Monitoring and measurement of processes

The Management is responsible for the establishment of a methodology and a system to monitor, measure and analyze the quality management system processes to assess whether processes are capable to achieve the planned results. When planned results are not achieved the need for correction and corrective action is discussed, as appropriate, in management oversight meetings (e.g. at Management Review, PGC, MOB, GMT, HOD meetings).

8.2.6 Monitoring and measurement of product

HSO has established and implemented planned and documented arrangements and procedures for the inspection and testing of product throughout the product realization process to verify that:

- Materials, sub-assemblies, and finished products meet the specified requirements at incoming, in-process, and final inspection
- Test/inspection equipment used and tester/inspector is documented as part of the test/inspection record
- Test/inspection records include all the appropriate evidence that the products have been inspected and tested per the appropriate procedures and arrangements and contains whether the products have passed or failed the inspections and tests according to defined acceptance criteria.
- Test/inspection records will be maintained and are kept as quality records
- Product release only occurs when all planned and documented arrangements are satisfactorily completed.
- The identity of the person responsible for the inspection, testing and release of product is documented.

The QA department is responsible to verify that the requirements, procedures and arrangements for monitoring and measurement of product are being followed.

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8.3. Control of non-conforming product

8.3.1 General

Each employee of HSO has the authority and responsibility to report any nonconformity at any stage of the process. The QA department has the responsibility for control of nonconforming products as well as the authority to stop manufacturing and / or shipment of any products found not to meet specified requirements. The decision will take into consideration the safety, efficacy, customers, regulatory and statutory requirements applicable to the product. HSO has established documented procedures with roles and responsibilities to identify, document, segregate, evaluate, and disposition non-conforming products. Records of the nature of the nonconformities and any subsequent action taken are maintained; these records include or refer to the associated evaluation, investigation or rationale for the decisions taken. The QA department is responsible to verify that the requirements, and procedures related to the handling of nonconforming products are being followed.

8.3.2 Actions in response to nonconforming product detected *before* delivery between HSO sites and customers

For nonconforming product detected before delivery immediately containment actions will be taken to prevent unintended use or delivery.

Product and/or documentation or records that do not conform to specified requirements will be identified and held in a quarantine or different location for final disposition.

The QA department is responsible to review and approve actions to take to eliminate, rework, and re-evaluate nonconformities.

Nonconforming products can only be accepted by concession with documented QA approval; records of acceptance by concession must include the personnel authorizing the concession, the justification for the decision, and must be maintained and archived as quality record. Records of inspection, test and the final disposition are documented and maintained.

8.3.3 Actions in response to nonconforming product detected *after* delivery between HSO sites and customers

For nonconforming products detected after delivery between HSO sites:

For nonconforming product detected before delivery immediately containment actions will be taken to prevent unintended use or delivery.

Product and/or documentation or records that do not conform to specified requirements will be identified and held in a quarantine or different location for final disposition.

The QA department is responsible to review and approve actions to take to eliminate, rework, and re-evaluate nonconformities.

Nonconforming products can only be accepted by concession with documented QA approval; records of acceptance by concession must include the personnel authorizing the concession, the justification for the decision, and must be maintained and archived as quality record. Records of inspection, test and the final disposition are documented and maintained.

For nonconforming products detected after delivery to customers:

HSO sites conducts a risk assessment to determine the impact of the nonconformance to patient safety, product performance, and regulatory compliance.

The outcome of the nonconformance impact assessment is assessed and discussed in a Field Corrective Action Board to determine the need for any type of Field Safety Corrective Actions.

In the event that a Field Safety Corrective Action is warranted documented procedures are followed to execute

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this decision.

Records of outcome of the risk assessment, and decisions and actions taken are maintained.

8.3.4 Rework

Rework follows documented procedures and take into account any adverse effect of rework on the product.

Rework procedures are reviewed and approved in the same manner as original procedures.

After completion of rework the product is verified to ensure that it meets applicable original acceptance criteria and regulatory requirements. Records of rework are maintained.

8.4. Analysis of data

HSO Management has established a documented procedure on how to determine, collect, and analyze data generated by the quality management system in order to assess whether the Quality Management System is effective. When results are not satisfactory the need for correction and corrective action is discussed, as appropriate, in management oversight meetings (e.g. at Management Review, PGC, MOB, GMT, HOD meetings). Records of those meetings are maintained, and actions are documented in the minutes of respective meetings, where appropriate.

8.5. Improvement

8.5.1 General

HSO intends to continuously improve the effectiveness of the quality system, as well as medical device safety and performance through the use of the quality policy, quality objectives, audit results, post-market surveillance, data analysis, corrective and preventive actions, and management review.

Any changes proposed as part of continuous improvement are evaluated against the risk associated with that change.

8.5.2 Corrective action

HSO has established and implemented documented procedures to identify and implement corrective actions to eliminate causes of actual nonconformities for the purpose of preventing their recurrence that include but are not limited to the following:

- Review of suspected nonconformities, including complaints
- Determining causes for actual nonconformities
- Evaluating the need for action to ensure that nonconformities do not reoccur
- Determining and implementing actions needed; actions will be proportionate to the effects of the nonconformity encountered.
- Verification that the corrective actions proposed do not adversely affect the ability to meet regulatory, safety, or performance requirements applicable to the product
- Corrective actions are taken without any undue delay.
- Reviewing the effectiveness of the corrective action taken
- Recording and maintenance of the results of any investigation and of actions taken

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8.5.3 Preventive Action

Top management has established and implemented documented procedures to identify and implement preventive actions to eliminate causes of potential nonconformities for the purpose of preventing their occurrence that include but are not limited to the following:

- Determining potential nonconformities and their causes
- Evaluating the need for action to prevent nonconformities from occurrence
- Determining and implementing actions needed; actions will be proportionate to the effects of the nonconformity encountered.
- Verification that the preventive actions proposed do not adversely affect the ability to meet regulatory, safety, or performance requirements applicable to the product
- Reviewing the effectiveness of the preventive action taken
- Recording and maintenance of the results of any investigation and of actions taken

9.0 APPENDIX

QM-16-001 A1 Quality Policy

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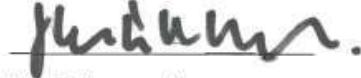
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QUALITY POLICY

HOYA Surgical Optics empowers cataract surgeons all over the world with innovative ophthalmic devices and services, with an attention to detail that helps them achieve better surgical outcomes and better practice results.

Our commitment to delivering these results is grounded upon a quality management system that is continuously improving to meet changing global regulatory requirements and our entrepreneurial drive to be the brand of first choice.

We achieve this by taking initiatives in developing required skills and competencies, reducing compliance and patient risks, and by strengthening our quality management system.



John Goltermann Lassen

Chief Executive Officer

*Established in August 2020, supersedes all previous versions within all HOYA Surgical Optics facilities.

Singularly Focused.
Globally Powered.



Signature Manifest

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Global Quality Manual

Document Review

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