Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

FINAL DOCUMENT

Title: Quality Management System-Medical Devices Requirements for Distributors, Importers and Authorized Representatives

Authoring Group: Work Group 7, Quality Management System: Operation & Implementation

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0 INTRODUCTION, PURPOSE AND SCOPE, DEFINITIONS

0.1 Preface

The document herein was produced by the Asian Harmonization Working Party (AHWP), a voluntary group of representatives from medical device regulatory authorities and the regulated industry. The document is intended to provide non-binding guidance for use in the regulation of medical devices, and has been subject to consultation throughout its development process.

0.2 Introduction

To ensure the safety, effective performance and quality of medical devices, a quality management system (QMS) has been required by regulatory authorities in many jurisdictions. Regulatory auditing is part of conformity assessment procedures in a medical device regulatory model. This applies to both manufacturers and distributors.

ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes, is widely accepted by regulators as the basis of the appropriate QMS requirements for medical device organizations that need to demonstrate its ability to provide medical devices and related services that consistently meet customer requirements and regulatory requirements applicable to medical devices and related services throughout the product lifecycle. ISO13485: 2016 specifies requirements for a quality management system that can be used by an organization involved in one or more stages of the life-cycle of a medical device, including design and development, production, storage and distribution, installation servicing and final decommissioning and disposal of medical devices, and design and development, or provision of associated activities.

A medical device distributor delivers medical devices provided by the manufacturer to further the medical device along the supply chain, and ultimately to the end users. A distributor may also provide services of medical devices. In some AHWP jurisdictions, distributors are required to comply with Good Distribution Practice (GDP). The distributor performs activities which are part of product lifecycle.

This document is intended to provide medical device distributor of AHWP member economies with the guidance on the implementation of quality management systems to ensure their conformity with ISO 13485: 2016 expectations. It has been prepared by Asian Harmonization Working Party Technical Committee Working Group 7. It is expected that the reader of this document is fundamentally proficient with the requirements of ISO 13485:2016.

0.3Rationale and Scope

0.3.1 Rationale

The activities of design and development, production, storage and distribution, installation servicing and final decommissioning and disposal of medical devices are implemented by the manufacturer under a documented quality management system in accordance with ISO 13485 and related regulatory requirements. The distributor must distribute, deliver or service medical devices to ensure the products meet the

requirements specified by the manufacturers and applicable regulatory requirements in their local market(s), and, as applicable, the manufacturer's local regulatory requirements.

Safety and performance of finished medical devices may be affected by various conditions such as warehouse conditions, transportation, installation, servicing, duration of storage, and user training. Collection of customer feedback and implementation of correction and corrective actions, post-market surveillance activities, implementation of field safety corrective actions for the associated medical devices may be conducted by the manufacturer through cooperation with its distributor. A documented quality management system for a distributor ensures the conformity of medical devices through its life cycle.

To ensure the medical device complies with the specifications and quality assurance requirements specified by the manufacturer, Asian Harmonization Working Party developed this guidance an organization which distributes medical devices.

Another purpose of this guidance document is to assist regulatory authorities and/or conformity assessment bodies in the planning and the performance for regulatory auditing of distributor under their jurisdiction i.e. the scope of activities subjected to auditing, the requirements and the basis for assessing conformity.

0.3.2 Scope

This guidance applies to an organization which distributes or imports medical devices in any market.

0.4 References

ISO 13485:2016 Medical devices — Quality management systems — Requirements for regulatory purposes

GHTF/SG1/N29:2005 Information Document Concerning the Definition of the Term 'Medical Device'.

0.5 Definitions

0.5.1 Distributor

A natural or legal person in the supply chain who, on his own behalf, furthers the availability of a medical device to the end user. (ISO 13485: 2016 3.5)

Note 1: An **Authorized Representative** is a natural or legal person established within a country or jurisdiction who has received a written mandate from the manufacturer to act on his behalf for specified tasks with regard to the latter's obligations under that country or jurisdiction's legislation. (ISO 13485: 2016 3.2)

Note 2: An **Importer** is a natural or legal person in the supply chain who is the first in a supply chain to make a medical device, manufactured in another country or jurisdiction, available in the country or jurisdiction where it is to be marketed. (ISO 13485: 2016 3.7)

Note 3: An Importer is a type of distributor in many AHWP jurisdictions. A Distributor (normally the Importer) may also be an Authorized Representative.

0.5.2 Manufacturer

Any natural or legal person with responsibility for design and/or manufacture of a medical device with the intention of making the medical device available for use, under his name; whether or not such a medical device is designed and/or manufactured by that person himself or on his behalf by another person(s). ISO 13485: 2016 3.10). This may also be referred to as the Product Owner in some regulatory jurisdictions

Note Manufacturer may be defined differently by AHWP member economies.

1 QUALITY MANAGEMENT SYSTEM FOR MEDICAL DEVICE DISTRIBUTOR

1.1 Structure of Guidance Text

The guidance text is based on Clause 4 to Clause 8 of the ISO13485 Standard. The guidance will initially state if the Clause is applicable for distributors, or not, and includes guidance text, as appropriate, on specific clauses or sub-clauses. The guidance shall reflect the specific needs for quality management systems for distributors / importers / authorized representatives.

"Additional Guidance for Requirements" – refer to guidance text to improve or supplement the actual clause in ISO13485, relating to the distributor / importer / authorised representative. This guidance can be adapted to be part of the regulatory framework for Good Distribution Practices (GDP)

"General Guidance for Clause" – refer to the notes that help the distributor / importer / authorized representative a better understanding in interpreting the clause relating to their organisation.

Quality Management System

ISO 13485: 2016 (Clause / Sub-Clause)	Clause Applicable?	Additional guidance for distributor, importer, and/or authorised representative
4.1 General requirements 4.1.1	Yes	**Additional Guidance for Requirements** The distributor, importer, and/or authorised representative defines the scope of its quality management system in accordance with the applicable ISO 13485:2016 The distributor, importer, and/or authorised representative defines and document its interaction with the manufacturer The distributor, importer, and/or authorised representative defines and document its communication, mutual agreement of performance expectations, with the manufacturer on the determination of the processes that affects product conformity with the applicable clauses of the standard and applicable regulatory requirements. **General Guidance for Clause:** Maintaining the effectiveness of the quality management system in its ability to meet customer and regulatory requirements will typically involve the organization responding effectively to external factors and internal issues. External factors can include: changes in regulatory requirements; customer feedback, including complaints and adverse event reports, and the results of post market surveillance. Internal issues can include: changes to the product line distributed overall performance of the organization; resource factors, including facilities, environment for the operation of the processes, including related software; human aspects such as competence of persons, including enhancing people skills

4.1.2		and introducing new competencies, organizational culture, changes in key personnel; operational factors such as delivery capabilities, performance of the competencies, organizational culture, changes in key personnel; performance of the quality management system including software related to the quality management system, customer evaluation; factors in the governance of the organization, such as rules and procedures for decision making or organizational structure; performance of the imported/distributed product. The organization can maintain the effectiveness of its established quality management system through a range of activities. Examples of activities to maintain an effective quality management system include defining and promoting processes which lead to achieving regulatory compliance; acquiring and using process data and information on a continuing basis; determining and deploying resources, including human and information system resources. Inputs such as the following should be considered: • the defined scope of the organization's quality management system; • products imported/distributed and services provided; • regulatory requirements; such as complaint handling and post-market surveillance • performance indicators such as: • on-time delivery, service response time; service outage trends; • organizational structure and responsibilities.

4.1.3		The outputs of the activities listed above can include: • documented procedures; • process flow maps (sequences, interrelationships and authorities or responsibilities, risks and defined criteria); • quality management system performance data (KPIs) Having identified the processes needed for the quality management system, and the risks associated with that process, the organization can look in detail at each process. Outsourcing is the use of an external provider to undertake an activity on behalf of the organization. Outsourcing is a strategic decision of the organization and implies a deeper relationship between the two parties than a straightforward supplier-customer purchasing interaction of placing an order and receiving materials. An organization may decide to outsource activities such as: • finance; • human resources; • customer interfaces such as call centres; • logistics; • calibration;
4.1.4		• maintenance; • servicing; • installation.
4.1.5		The relationship with the external provider of outsourced activities is managed in accordance with the Purchasing controls specified in 7.4, with the level of control being determined based on the risk of the activity on the safety and performance of the medical device and the contribution of the activity to regulatory compliance.

4.1.6		Outsourcing does not remove the organization's responsibility for the activity being outsourced and the organization has to maintain the necessary oversight to make sure that the activity is undertaken in accordance with the agreed requirements. Software used in the quality management system itself, such as: • as an element of enterprise resource planning (ERP) platforms; • for management of documents; • for recording and managing nonconformities, corrective actions or preventive actions; • for managing and recording internal audits; • for managing actions arising from external audits; • for managing calibration of measuring devices • for analysis of data on the performance of the quality management system. are considered. The important aspects of validation of software in this context is demonstrating that the way that the software is used (its application) is suitable and that the outcome is effective. For example, a spreadsheet might be programmed to perform specific calculations when data is entered as part of data analysis; the results of the calculations need to be verified and the spreadsheet protected from inadvertent changes.
4.2 Documentation requirements 4.2.1 General	Yes	**Additional Guidance for Requirements** For each type or model of medical device, the distributor, importer, and/or authorised representative should establish and maintain a file either containing or referencing

		documents defining product specifications and quality management system requirements which apply to the distributor, importer, and/or authorised representative. These documents shall define the complete distribution process and, if applicable, installation and servicing. **General Guidance for Clause** The extent of the quality management system documentation can differ from one organization to another due to a) the size of the organization; b) the type of activities undertaken; c) the complexity of processes and their interactions; and, d) the skills and qualifications of the organization's personnel performing the activities in question. Procedures or instructions may be presented in text, graphic or audio-visual form. Documented procedures, including work instructions and flowcharts, should be stated simply, unambiguously and understandably, and should indicate methods to be used and criteria to be satisfied. These procedures typically define activities and describe what is to be done, and by whom, when, where and how it is to be done, what materials, equipment and documents are to be used, is to be monitored and measured, and what records are required. Documentation should be evaluated with respect to the effectiveness of the quality management system against criteria, such as functionality, human interfaces, resources required, policies and objectives, and interfaces used by the organization's customers and suppliers.

4.2.2 Quality manual	Yes	**Additional Guidance for Requirements** The scope of quality management system of a distributor, importer, and/or authorised representative is defined in accordance with this guidance and applicable regulatory requirements. No general guidance for clause required.
4.2.3 Medical device file	Yes	**Additional Guidance for Requirements** For each medical device type or medical device family, the distributor should establish and maintain a one or more files **General Guidance for Clause** These documents (either filed or referenced) shall define the complete distribution process and, if applicable, installation and servicing.
4.2.4 Control of documents	Yes	**Additional Guidance for Requirements** The retention period of documents is defined in accordance with the requirements specified by the manufacturer and/or applicable regulatory requirements. **General Guidance for Clause** Document control should, at minimum: assign responsibilities for preparation, approval and issue of documents, ensure prompt withdrawal of obsolete copies of controlled documents, define a method for recording the implementation date of a document change, and allow controlled and non-controlled documents to be distinguished. The quality management system may also identify recipients of controlled copies of documents. Documents may be reviewed at

		various times throughout the life of a document, for example, as a result of facilities, process, product, personnel or organizational changes, internal, external and third party audit activities, acquisitions, new products imported and/or old products withdrawn from distribution, technologies or software, requirement of the organization's quality management system for periodic review.
4.2.5 Control of records	Yes	**Additional Guidance for Requirements** The retention period of the records is defined in accordance with the requirements specified by the manufacturer or applicable regulatory requirements. **General Guidance for Clause** Records that could contain Confidential Health information. Such confidential information might be subject to particular regulatory requirements for privacy is some jurisdictions. Hand-written entries should be made by indelible medium. Persons making authorized entries on records or verifying such entries should do so in clear legible writing, and should confirm the entry by adding their initials, signature or equivalent, and the date. Good recording practices can include the following procedures, as appropriate: enter data and observations as they occur; do not pre date or post-date records; do not use another person’s initial, signature or equivalent; complete all fields or check-offs when using a form;

		refer to raw data when transferring data, and have the transcription verified by a second person; verify all entries for completeness and correctness; number pages to ensure completeness. If an error is made or detected on a record, it should be corrected in such a manner that the original entry is not lost and the correction is initialled and dated. If appropriate, the reason for the correction should be recorded. Where electronic records systems are used in place of paper-based ones, these systems should, wherever possible, incorporate time-stamped, immutable, system-generated audit trails, for tracking changes. Such audit trails may include the identity of the authorized user, creations, deletions, modifications/ corrections, time and date, links and embedded comments. The organizations may have alternative provisions for critical data entry of electronic records, for example, a second authorized person with logged name and identification, with time and date, can verify data entry via the keyboard, or systems with direct data capture can have the second check as a part of validated system functionality. A system should be implemented that assures the integrity of electronic records and protects against unauthorized entries. Applicable regulatory requirements may have organizations establish documented procedures specifically for control of electronic records. This might include, but not limited to, access, storage, reproducibility, readability, audit trails and electronic signatures.

Management responsibility

ISO 13485: 2016 (Clause / Sub-Clause)	Clause Applicable?	Additional guidance for distributor, importer, and/or authorised representative
5 Management responsibility 5.1 Management commitment	Yes	There is no specific guidance for this clause. Note: The distributor shall ensure the requirements specified by the manufacturer or applicable regulatory requirements.
5.2 Customer focus	Yes	There is no specific guidance for this clause. Note: Irrespective of who undertakes the interactions with customers and regulatory bodies, it is the responsibility of top management to make certain that these requirements are understood and that the necessary resources are available
5.3 Quality policy	Yes	There is no specific guidance for this clause.
5.4 Planning 5.4.1 Quality objectives	Yes	There is no specific guidance for this clause. Note: The quality objectives shall include the requirements specified by the manufacturer to be aligned with the importer / distributor
5.4.2 Quality management system planning	Yes	There is no specific guidance for this clause.
5.5. Responsibility, authority and communication	Yes	There is no specific guidance for this clause.

5.5.1 Responsibility and authority		
5.5.2 Management representative	Yes	There is no specific guidance for this clause. Note: Management shall demonstrate with objective evidence for assignment of management representative
5.5.3 Internal communication	Yes	There is no specific guidance for this clause.
5.6 Management review 5.6.1 General	Yes	**Additional Guidance for Requirements** Management shall demonstrate, with objective evidence, management commitment through the establishment of the quality management system, and adherence to the quality policy, procedures and objectives defined for the distributor/ importer/ authorized representative
5.6.2 Review input	Yes	**General Guidance for Clause** Review input can include: • feedback; complaint handling; reporting to regulatory authorities; • audits; • monitoring and measurement of processes and product • corrective action; preventive action; • follow-up actions from previous management reviews; • changes that could affect the quality management system; • recommendations for improvement; • applicable new or revised regulatory requirements

5.6.3 Review output	Yes	**General Guidance for Clause** • improvement needed to maintain the suitability, adequacy, and effectiveness of the quality management system and its processes; • improvement of product related to customer requirements; • changes needed to respond to applicable new or revised regulatory requirements; • resource needs.

Resource management

ISO 13485: 2016 (Clause / Sub-Clause)	**Clause Applicable?**	**Additional guidance for distributor, importer, and/or authorised representative**
6.1 Provision of resources	Yes	**Additional Guidance for Requirements** The distributor / importer / authorized representative needs to identify all human, physical (materials, services, supplies, work environment, infrastructure, plant/building, equipment/machinery (monitoring & measuring, utilities and support services) and information required for the implementation and maintenance of an effective quality management system. These requirements need to meet the organization's requirements in furthering the availability of a medical device to the end user (i.e. delivery and/or installation and/or servicing (preventive maintenance or repair) of a medical device), conforms to customer requirements, and complies with applicable regulatory requirements. Responsibility for the provision of resources resides with the organization regardless of whether associated processes

		are performed by the organization itself or are outsourced. **General Guidance to Clause** Example of changes that may affect resources include: • Changes in regulations, statutes (both medical device and non-medical device related), markets, customer expectations, technical or management system standards. • Changes to organizations objectives (focus on new products, new process or shifted targets); • Addition or termination of outsource service providers or significant sub-contractors/suppliers; • Foreseeable loss of capability – scheduled leave of certain personnel, holidays, scheduled equipment maintenance (including associated temporary plant shutdown to accommodate major maintenance); • Increase or reduction of personnel size; • Unplanned loss of capability – death or unscheduled personnel leave, major breakdown, fuel/energy shortage, man-made or natural disasters; • Changes brought about by management decision including results of Management Reviews
6.2 Human resources	Yes	There is no specific guidance for this clause. Objective proof of competence in the human resources, and a risk based approach to training for competency, including suppliers, is required.
6.3 Infrastructure	Yes	**Additional Guidance for Requirements** The distributor / importer / authorized representative determines, provides, and

		maintains the infrastructure needed to achieve conformity to product requirements as specified by the manufacturer. Document the requirements for the infrastructure needed to achieve conformity to product requirements, prevent product mix-up and ensure orderly handling of product. ▪ buildings, workspace and utilities; ▪ supporting services (such as transport, communication, or information systems). Document requirements for the maintenance activities, and including the interval of performing the maintenance activities, when such maintenance activities, or lack thereof, can affect product quality. **General Guidance for Clause** Infrastructure refers to system of buildings, workspace, which can include, but not limited to, furniture, lighting and other fixtures & fittings) & associated utilities (energy (electricity, gas, fuel or other) water), equipment and supporting services (such as transport (e.g. conveyor systems, lifting equipment, forklifts, trucks, trailers, refrigerated containers, communication or information technology – computer network including RFID & bar code readers, Enterprise Resource Planning, vehicle tracking, systems Tools and equipment used for maintenance shall be maintained. The rationale of maintenance requirements and intervals should be based on the equipment manufacturer's recommendations as reflected in equipment manuals, maintenance schedules, instructions, formats/ checklist provided by the equipment manufacturer. The maintenance schedule should normally be posted on or near the equipment, or should be readily available. Maintenance

		should be carried out on schedule and appropriate records maintained. In addition to preventive maintenance logs, detailed records on part replacement as well as equipment modification and repair maintenance will need to be maintained. The organization should ensure that the buildings and workspace utilized are of suitable design and contain adequate space to facilitate cleaning, maintenance and other necessary operations. The premises should be laid out in such a way, and with sufficient allocation of space, to facilitate orderly handling and to prevent mixing between material (including labels), work in progress items, material scrapped, re-worked, modified or repaired, any other nonconforming material, medical devices, equipment, inspection aids, documents and drawings. Beyond physical maintenance of building, workspace and support services, the distributor / importer / authorized representative will need to ensure the maintenance of the capability the infrastructure provides. Maintaining capability means maintaining the output of such infrastructure where there is a computer virus, a fire, a gas explosion, a power or water cut, disruption in telecommunication lines, unavailability of equipment spare parts or any other man-made events or natural disasters which would the existing building, process equipment or supporting services no longer operational and/or serviceable. Contingency plans, disaster recovery plans and business continuity provisions would benefit the organization.
6.4 Work environment and contamination control: 6.4.1 Work environment	Yes	**Additional Guidance for Requirements** The distributor / importer / authorized representative determines and manages the work environment needed to achieve conformity to product requirements as

6.4.2 Contamination control		specified by the manufacturer, plans and documents for contamination control in accordance with the requirements as specified by the manufacturer. Identify which aspects of the work environment, for activities within the supply chain that the organization is responsible for, that can result in negative impact to the product quality (safety, performance and function of the medical device). **General Guidance to Clause** Take note of: ▪ conditions within the work environment established - maintenance of appropriate sanitation and hygiene (e.g. washrooms, food and drink preparation) ▪ the personnel within that work environment - appropriate customer waiting areas and facilities Any personnel, including those entering the area on a temporary or transient basis, who can be in contact with product or work environment, must be suitably clothed, clean and in good health if these factors could adversely affect the product. This is because individuals spread both microorganisms and particles, which constitute contamination risks. Examples of persons who might enter the work environment are: ▪ material handlers, ▪ quality control, quality assurance, ▪ suppliers of any material or service (including cleaning services, process and building maintenance), ▪ customers, visitors, auditors Persons who have a medical condition that can adversely affect the product must be

		excluded from those operations, or **prevented from entry** into such areas **until they have recovered**. Special training and/or supervision should be provided to persons required to perform work under special environmental conditions, **including temporary personnel** (which should have their presence supervised by someone whom in turn is suitably competent) Ensure those whom work in such controlled environments are made competent of related work operation requirements, and such competence is maintained (see Clause 6.2) ▪ the storage conditions and conditions during the distribution cycle. ▪ temperature, ▪ humidity, ▪ airflow, air filtration, air ionization, ▪ pressure differentials, ▪ Lighting (both spectral content and intensity), ▪ sound, vibration, ▪ cleanliness of work surfaces and process, ▪ water quality, ▪ number of people in the work environment. Of importance are medical devices which are to be supplied for purposes in which microbiological cleanliness is of significance. The organization should also consider ergonomics and the impact of human factors in achieving and maintaining product conformity and achievement of quality objectives for the activities it conducts and/or is responsible for.

		Examples of situations in which the work environment can influence product quality include handling medical devices that: • are intended by the manufacturer to be used in a sterile manner; • have a limited shelf life; • have special handling or storage requirements; • are susceptible to electrostatic discharge (ESD) due to electronic microcircuits or imbedded software, and • are affected in their use by microbiological and/or particulate cleanliness or other environmental conditions. Sources of unwanted effects from equipment utilized which could potentially impact the other equipment, the work environment and products include heat, vibration, noise, magnetism, electromagnetic interference, induced current, radiation, etc. Work environment should be designed and equipped to prevent entry of insects, reptiles, rodents, birds and other pests/animals. Pest controls activities must be determined to not to pose any risk of toxicological or biological contamination to the product, equipment and or work environment. Note: In certain jurisdictions, activities which involve the breaching of the primary package of sterile medical devices will render the organization as a manufacturer – in such an event, the organization's quality management system needs to meet requirements and expectations applicable to that of a manufacturer.

Product realization

ISO 13485:2016	Clause Applicable?	Additional guidance for distributor, importer, and/or authorised representative

7 Product realization 7.1 Planning of product realization	Yes	**Additional Guidance for Requirements:** The distributor shall plan to meet requirements for preservation (See Clause 7.9) of product quality through handling, storage, distribution, traceability, installation and servicing if these are applicable Output of this planning shall be suitable for the organization method of operation and documented.
7.2 Customer-related processes 7.2.1 Determination of requirements related to the product	Yes	**Additional Guidance for Requirements** Applicable to the distributor with respect to the manufacturer's requirements. Such as requirements for delivery and user training. Determine: a) requirements specified by the customer, including the requirements for delivery and post-delivery activities; b) requirements not stated by the customer but necessary for specified or intended use, as known; **General Guidance for Clause** The organization can look at some essential elements that need to be addressed for each product. Aspects to consider include: - requirements for transportation including mode of delivery and post-market activities - Requirements for the intended purpose of products. - Any user training to ensure specific performance and safe use of the product

		- Any regulatory requirements.
7.2.2 Review of requirements related to the product	Yes	**Additional Guidance for Requirements** Applicable to the distributor, importer, and/or authorised representative with respect to the regulatory and manufacturer's requirements. **General Guidance for Clause** This review shall be conducted prior to the organization's commitment to supply product to the customer to ensure that: - Product requirements are documented & defined - Contract or ordering requirements differing from those previously indicated are resolved - Applicable regulatory requirements are met - User training identified is available or planned to be available - Organization can meet the defined requirements.
7.2.3 Communication	Yes	**Additional Guidance for Requirements** The distributor, importer, and/or authorised representative shall determine and implement effective arrangements for communicating with customers in accordance with the requirements specified by the manufacturer, if applicable.

		The distributor shall communicate with regulatory authority. The organization shall define and document the arrangement for communication with customers for the following types of documents: • Product information • Enquiries, contracts or order handling including changes: • Customer feedback including complaints • Advisory notices • in relating to customer complaints and field actions including recall with the manufacturer if required by regulatory requirements.
7.3 Design and development 7.3.1 General	No	This clause is not applicable to the distributor, importer, and/or authorized representative.
7.3.2 Design and development planning	No	This clause is not applicable to the distributor, importer, and/or authorized representative.
7.3.3 Design and development inputs	No	This clause is not applicable to the distributor, importer, and/or authorized representative
7.3.4 Design and development outputs	No	This clause is not applicable to the distributor, importer, and/or authorized representative.
7.3.5 Design and development review	No	This clause is not applicable to the distributor, importer, and/or authorized representative.

7.3.6 Design and development verification	No	This clause is not applicable to the distributor, importer, and/or authorized representative.
7.3.7 Design and development validation	No	This clause is not applicable to the distributor, importer, and/or authorized representative.
7.3.8 Design and development transfer	No	This clause is not applicable to the distributor, importer, and/or authorized representative.
7.3.9 Control of design and development changes	Yes	**Additional Guidance for Requirements** Distributor, importer, and/or authorized representative is expected to notify manufacturer of planned changes that may affect the product which may include: - changes in storage location - changes in mode of transportation - changes related to product handling. - Other changes where appropriate
7.3.10 Design and development files	No	This clause is not applicable to the distributor, importer, and/or authorized representative.
7.4 Purchasing 7.4.1 Purchasing process	Yes	**Additional Guidance for Clause** Applicable if the distributor, importer, and/or authorised representative purchases product or service that affects the quality of the final product. For example, the distributor, importer, and/or authorised representative might lease premises, have storage conditions that need monitoring such as cold rooms,

		use a third party for transport - all of which could require purchasing. **General Guidance for Clause** Criteria for supplier selection will be required as well as risk associated with the medical device, based on the supplier's ability to provide product that meets the organization's requirements, and based on the performance of the supplier.
7.4.2 Purchasing information	Yes	**Additional Guidance for Requirements** The distributor, importer, and/or authorized representative shall maintain purchasing information in accordance with the traceability requirement specified by the manufacturer. Any change would need to be notified to the manufacturer
7.4.3 Verification of purchased product	Yes	**Additional Guidance for Requirements** Establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchasing requirements. When distributor/importer/authorized representative becomes aware of any changes to the purchased products, impact assessment is required. Records are required to be maintained.
7.5 Production and service provision 7.5.1 Control of production and service provision	Yes	**Additional Guidance for Requirements** Specifically, this clause addresses the labelling and packaging activities carried out by a distributor/importer/authorized representative, if applicable

		General Guidance for Clause The organization shall establish and maintain a record (see 4.2.5) for each medical device or batch of medical devices that provides traceability to the extent specified in 7.5.9 and identifies the amount manufactured and amount approved for distribution. The record shall be verified and approved.
7.5.2 Cleanliness of product	Yes	**Additional Guidance to Requirements** a), b), d) and e) of this clause is not applicable to the distributor, importer, and/or authorized representative unless the organization has the following type of products: product is cleaned by the organization prior to sterilization or its use; - product cannot be cleaned prior to sterilization or its use, and its cleanliness is of significance in use; - product is supplied non-sterile and is to be subjected to a cleaning process prior to sterilization or its use; - product is supplied to be used non-sterile, and its cleanliness is of significance in use
7.5.3 Installation activities	Yes	**Additional Guidance for Requirements** Applicable to the distributor, importer, and/or authorized representative carries out installation in accordance with the requirements specified by the manufacturer.

		General Guidance to Clause Organization shall provide documented requirements for medical device installation and verification of installation Records performed by organization or its supplier is required to be maintained.
7.5.4 Servicing activities	Yes	**Additional Guidance for Requirements** Applicable if the distributor /importer/authorised representative conducts servicing activities in accordance with the requirements specified by the manufacturer. Regulatory requirements may define the servicing activities applicable to the distributor, importer, and/or authorised representative. To determine if service records is to be handled as a complaint
7.5.5 Particular requirements for sterile medical devices	No	This clause is not applicable to the distributor, importer, and/or authorised representative.
7.5.6 Validation of processes for production and service provision	No	This clause is not applicable to the distributor, importer, and/or authorised representative.
7.5.7 Requirements for validation of processes for sterilization and sterile barrier systems	No	This clause is not applicable to the distributor, importer, and/or authorized representative.
7.5.8 Identification	Yes	**Additional Guidance for Requirements** The distributor, importer, and/or authorized representative shall identify the product with the suitable means as

		specified by the manufacturer or applicable regulatory requirements
7.5.9 Traceability 7.5.9.1 General	Yes	**Additional Guidance for Requirements** The distributor, importer, and/or authorized representative shall implement documented procedures for traceability as specified by the manufacturer or applicable regulatory requirements
7.5.9.2 Particular requirements for implantable medical devices	Yes	**Additional Guidance for Requirements** The first paragraph of this clause is not applicable to the distributor, importer, and/or authorised representative.
7.5.10 Customer property	Yes	**Additional Guidance for Requirements** "Customer Property" is defined as including: Measurement Equipment Raw Materials Product Confidential Health Information
7.5.11 Preservation of product	Yes	**Additional Guidance for Requirements** The distributor, importer, and/or authorized representative establishes documented procedures or work instructions in accordance with the requirements specified by manufacturer for preserving the conformity of product during delivery to the intended destination including special storage and transportation conditions, if applicable. The second paragraph of this clause is not applicable to the distributor.

7.6 Control of monitoring and measuring devices	Yes	**Additional Guidance for Requirements** The approach and activities associated with validation and revalidation of the software used for monitoring and measurement shall be established in accordance with the requirements specified by the manufacturer.

Measurement, analysis and improvement

ISO 13485: 2016	**Clause Applicable?**	**Additional guidance for distributor, importer, and/or authorised representative**
8 Measurement, analysis and improvement 8.1 General	Yes	**Additional Guidance for Requirements** Documented procedure shall be established for inspection and testing activities are required and as defined by the manufacturer, if applicable. **General Guidance for Clause** This should include methods of sampling and testing for the entire processes. Statistical methods are to be used to define the release and acceptance criteria. Relevant data should be shared with different departments
8.2 Monitoring and measurement 8.2.1 Feedback	Yes	**Additional Guidance for Requirements** The distributor/importer/authorised representative shall document feedback applicable to the product and its supply from the post-production phase in accordance with the requirements specified by the manufacturer and applicable regulatory requirements.

		General Guidance for Clause Establish a documented procedure to collect, analyse and use information to monitor quality problems. There are many sources to collect such information whether the customer requirements are met or not. Some examples for such collection are customer surveys, service delivery data, regulatory authority website reviews, customer complaints. This will help to provide early warning of vigilance or post marketing surveillance, quality problems
8.2.2 Complaint handling	Yes	There is no specific guidance for the distributor/ importer / authorized representative.
8.2.3 Reporting to regulatory authorities	Yes	**Additional Guidance for Requirements** The distributor / importer / authorised representative may be responsible for reporting to the regulatory authorities on behalf of the manufacturer, if applicable. The complaint handling procedure should also include the requirements that meet certain criteria such as for adverse events
8.2.4 Internal audit	Yes	**General Guidance for Clause** Establish a documented procedure for performing internal audit/s and ensure that all requirements are addressed in the procedure. The responsibilities of auditing process must be defined clearly such as who will plan and who will conduct, how and at what frequency. The qualification process of auditors and independency to be mentioned in the procedure. There should be a standard format to document the observations and responses should be defined. The review mechanism for the effectiveness of this audit process has to be defined. The process of investigation and

		addressing the observations such as corrective and preventive actions for each observation should be defined in the procedure. Note: The distributor may outsource internal audit process if it is a small business
8.2.5 Monitoring and measurement of processes	Yes	There is no specific guidance for the distributor/ importer / authorized representative **General Guidance for Clause** Define processes to be monitored and measured
8.2.6 Monitoring and measurement of product	No	This clause is not applicable to the distributor / importer / authorized representative
8.3 Control of nonconforming product 8.3.1 General	Yes	**Additional Guidance for Requirements** The second paragraph of this clause is not applicable to the distributor. Note: The distributor manages a non-conformance if it occurs within their own quality system. Disposition of product is determined either by the manufacturer or jointly with the distributor / importer / authorized representative
8.3.2 Actions in response to nonconforming product detected before delivery	No	This clause is not applicable to the distributor / importer / authorized representative as it is not within the organization's scope per definition
8.3.3 Actions in response to nonconforming product detected after delivery	Yes	There is no specific guidance for the distributor/ importer / authorized representative
8.3.4 Rework	No	This clause is not applicable to the distributor / importer / authorized representative as it is not within the organization's scope per definition

8.4 Analysis of data	Yes	There is no specific guidance for the distributor/importer/authorized representative
8.5 Improvement 8.5.1 General	Yes	**Additional Guidance for Requirements** Establish documented procedures for the issue and implementation of advisory notices in accordance with the requirements specified by the manufacturer or applicable regulatory requirements. Maintain the records of customer complaint investigations and share the information with the manufacturer/ authorized representative Establish documented procedures to the notification of adverse events or recall on behalf of the manufacturer that meet national regulatory authority specified reporting criteria to the national regulatory authority or its designated organization, if applicable. **General Guidance for Clause** Improvement activities are those which identify and implement any changes necessary to ensure and maintain the continued suitability and effectiveness of the quality management system to meet the requirements of the customer.
8.5.2 Corrective action	Yes	**Additional Guidance for Requirements** Implement corrective actions as specified by the manufacturer per quality agreement or per applicable regulatory requirements An important element in the programme is the dissemination of information on corrective actions to those directly responsible for ensuring quality. Corrective

		action should be implemented without undue delay.
8.5.3 Preventive action	Yes	**Additional Guidance for Requirements** Implement preventive actions as specified by the manufacturer per quality agreement or per applicable regulatory requirements

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