TERMS AND DEFINITIONS

**Advisory notice** — A notice issued by the organization, subsequent to delivery of the medical device, to provide supplementary information and/or to advise what action should be taken in the use of a medical device, the modification of a medical device, the return of the medical device to the organization that supplied it, or the destruction of a medical device.

**As appropriate** — In the standard, several requirements are qualified by the phrase “as appropriate;” such requirements are considered appropriate if they are necessary for:
- a product to meet requirements.
- compliance with applicable regulatory requirements.
- the organization to carry out corrective action.
- the organization to manage risks.

This drives much of the “risk-based thinking” throughout the standard. Further, whenever the standard qualifies a requirement by the phrase “as appropriate,” the reader must understand that it is always considered to be appropriate unless the organization can justify otherwise. Formal documentation of the rationale for exclusion of any requirement qualified by the phrase “as appropriate” would need to be documented.

**Authorized representative** — 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.

**Clinical evaluation** — Assessment and analysis of clinical data pertaining to a medical device to verify the clinical safety and performance of the device when used as intended by the manufacturer.

**Complaint** — A written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, usability, safety, or performance of a medical device that has been released from the organization’s control or related to a service that affects the performance of such medical devices.

**Distributor** — Natural or legal person in the supply chain who, on his own behalf, furthers the availability of a medical device to the end user.

Note the following:
- More than one distributor may be involved in the supply chain.
- Persons in the supply chain involved in activities such as storage and transport on behalf of the manufacturer, importer, or distributor are not distributors under this definition.
Implantable medical device — A medical device which can only be removed by medical or surgical intervention and is intended to:
- be totally or partially introduced into the human body or a natural orifice.
- replace an epithelial surface or the surface of the eye.
- remain after the procedure for at least 30 days.

Note: This definition of implantable medical devices includes active implantable medical devices.

Importer — 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.

Labeling — A label, instructions for use, and any other information that is related to identification, technical description, intended purpose, and proper use of the medical device, but excluding shipping documents.

Life-cycle — All phases in the life of a medical device, from the initial conception to final decommissioning and disposal.

Manufacturer — 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).

Note the following:
- This “natural or legal person” has ultimate legal responsibility for ensuring compliance with all applicable regulatory requirements for the medical devices in the countries or jurisdictions where it is intended to be made available or sold, unless this responsibility is specifically imposed on another person by the Regulatory Authority (RA) within that jurisdiction.
- The manufacturer’s responsibilities are described in Global Harmonization Task Force (GHTF) guidance documents. These responsibilities include meeting both pre-market requirements and post-market requirements, such as adverse event reporting and notification of corrective actions.
- “Design and/or manufacture,” as referred to in the above definition, may include specification development, production, fabrication, assembly, processing, packaging, repackaging, labelling, relabeling, sterilization, installation, or remanufacturing of a medical device; or putting a collection of devices, and possibly other products, together for a medical purpose.
- Any person who assembles or adapts a medical device that has already been supplied by another person for an individual patient, in accordance with the instructions for use, is not the manufacturer, provided the assembly or adaptation does not change
the intended use of the medical device.

- Any person who changes the intended use of, or modifies, a medical device without acting on behalf of the original manufacturer and who makes it available for use under his own name, should be considered the manufacturer of the modified medical device.
- An authorized representative, distributor, or importer who only adds its own address and contact details to the medical device or the packaging, without covering or changing the existing labelling, is not considered a manufacturer.
- To the extent that an accessory is subject to the regulatory requirements of a medical device, the person responsible for the design and/or manufacture of that accessory is considered to be a manufacturer.

Medical device family — group of medical devices manufactured by or for the same organization and having the same basic design and performance characteristics related to safety, intended use and function.

Medical device — An instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material, or other similar or related article, intended by the manufacturer to be used alone or in combination for human beings for one or more specific medical purpose including the following:
- diagnosing, preventing, monitoring, treating, or alleviating disease.
- diagnosing, monitoring, treating, alleviating, or compensating for an injury.
- investigating, replacing, modifying, or supporting of the anatomy or of a physiological process.
- supporting or sustaining life.
- controlling conception.
- disinfecting medical devices.
- providing information for medical purposes by means of in vitro examination of specimens derived from the human body, and does not achieve its primary intended action by pharmacological, immunological, or metabolic means, but may be assisted in its function by such means.

Note: Products that may be considered to be medical devices in some jurisdictions but not in others include: disinfection substances; aids for persons with disabilities; devices incorporating animal and/or human tissues; devices for in vitro fertilization or assisted reproduction technologies.

Nonconformity — The non-fulfillment of a requirement.

Objectives — The results to be achieved. Please note the following:
- An objective can be strategic, tactical, or operational.
- Objectives can relate to different disciplines (e.g., financial, health and safety,
and environmental objectives) and can apply at different levels (e.g., strategic, organization-wide, project, product, and process).

- An objective can be expressed in other ways (e.g., as an intended outcome, a purpose, an operational criterion) as a quality objective or by the use of other words with similar meaning (e.g., aim, goal, or target).
- In the context of quality management systems quality objectives are set by the organization, consistent with the quality policy, to achieve specific results.

**Performance evaluation** — Assessment and analysis of data to establish or verify the ability of an *in vitro* diagnostic medical device to achieve its intended use.

**Policy** — Intentions and direction of an organization as formally expressed by its top management.

**Post-market surveillance** — Systematic process to collect and analyze experience gained from medical devices that have been placed on the market.

**Process** — A set of interrelated or interacting activities that use inputs to deliver an intended result.

Note: Whether the “intended result” of a process is called *output*, *product*, or *service* depends on the context of the reference.

**Product** — The result of a process.

Note that the definition of “product” differs from the definition given in ISO 9000:2015, and that there are four generic product categories, as follows:

- services [which are the result of at least one activity necessarily performed at the interface between the supplier and customer and is generally intangible (e.g., transport)].
- software [which consists of information, is generally intangible, and can be in the form of approaches, transactions, or procedures (e.g., a computer program, a dictionary)].
- hardware [which is generally tangible and its amount is a countable characteristic (e.g., an engine mechanical part)].
- processed materials [which are generally tangible and their amount is a continuous characteristic (e.g., lubricant)].

**Purchased Product** — Product provided by a party outside the organization’s quality management system.

**Quality** — The degree to which a set of inherent characteristics of an object fulfills requirements.
Quality management — Coordinated activities to direct and control an organization with regard to quality.

Quality policy — The overall intentions and directions of an organization as formally expressed by its top management with regard to quality.

Records — Document stating results achieved or providing evidence of activities performed.

Note: Records can be used to formalize traceability and to provide evidence of verification, preventive action, and corrective action.

Risk — Combination of the probability of occurrence of harm and the severity of that harm.

Risk management — Systematic application of management policies, procedures, and practices to the tasks of analyzing, evaluating, controlling, and monitoring risk.

Scope — Relates to those activities within the boundaries of the system and includes the applicable standards, documents, products, processes, personnel, and locations.

Sterile barrier system — Minimum package that prevents ingress of microorganisms and allows aseptic presentation of the product at the point of use.

Sterile medical device — A medical device intended to meet the requirements for sterility.