PROPOSED DOCUMENT

International Medical Device Regulators Forum

Title: Principles of Labeling for Medical Devices and IVD Medical Devices

Authoring Group: IMDRF Good Regulatory Review Practices

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Table of Contents

Preface

The document herein was produced by the International Medical Device Regulators Forum (IMDRF), a voluntary group of medical device regulators from around the world. The document has been subject to consultation throughout its development.

Introduction

The purpose of this IMDRF guidance is to provide globally harmonized labeling principles for medical devices and IVD medical devices and support the IMDRF Essential Principles of Safety and Performance. Specifically, this document provides guidance on the content of the label and instructions for use in order to support the correct, safe, and effective use of medical devices and IVD medical devices by their users.

This document has been developed to encourage and support global convergence of regulatory systems. It is intended for use by Regulatory Authorities (RAs), Conformity Assessment Bodies (CABs), industry, and others, and will provide benefits in establishing consistent labeling requirements in various jurisdictions.

Labeling[1] serves to identify a device and its manufacturer, and to communicate information on safety, use and performance. In some jurisdictions, Labeling is referred to as 'Information Supplied by the Manufacturer'. Labeling includes the label, instructions for use, and information related to the identification, technical description, intended purpose and proper use of the medical device and IVD medical device, as applicable (Figure 1). It is intended for users of medical devices, including IVD medical devices, both professional and lay persons, as appropriate, and for relevant third parties.

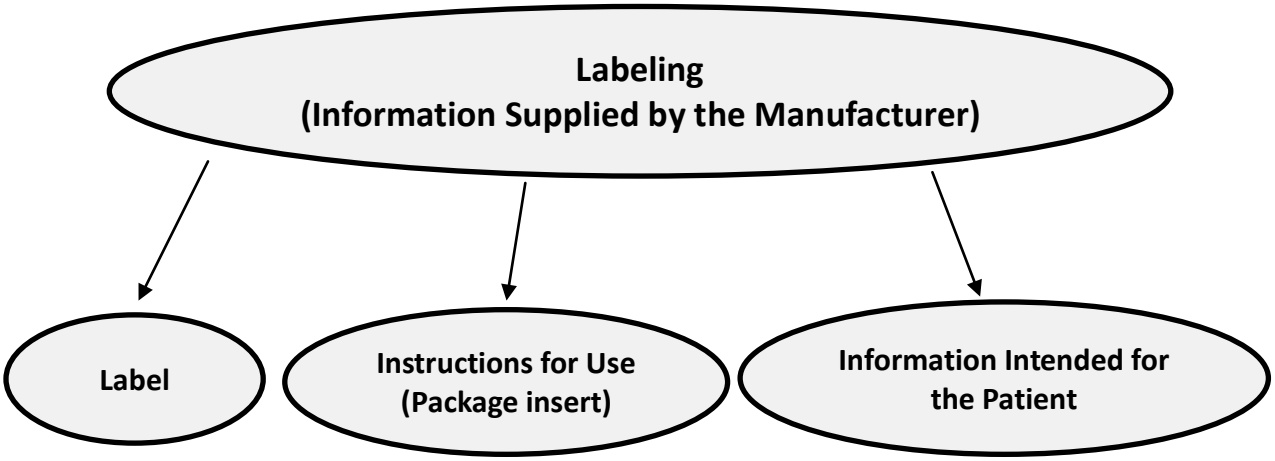

Figure 1. Components of Medical Device and IVD Medical Device Labeling

RAs require and specify information that manufacturers are expected to incorporate in the labeling when the device is placed onto the market, to ensure the correct, safe, and effective use of their product. This guidance provides some of those basic expectations, although RAs may have additional labeling requirements beyond the scope of this guidance.

[1] Some regional and national regulations use the term 'information supplied by the manufacturer' rather than 'labeling'. This document uses the term 'labeling'.

This guidance document describes the general labeling principles for medical devices and IVD medical devices and supersedes an earlier version produced under the Global Harmonization Task Force (GHTF) entitled "Label and Instructions for Use" dated September 16, 2011 (GHTF/SG1/N70:2011). The intent of this document is to outline the foundational labeling principles that are globally harmonized. It is important to note that many jurisdictions have additional specific labeling requirements which sometimes also depend on the particular medical device or IVD medical device.

1.0 Scope

This document applies to all medical devices and IVD medical devices and is intended to specify the general content and format of medical device and IVD medical device labeling. This document specifies the general labeling principles, including specific sections on the label, instructions for us, and information intended for the patient. The requirements of any relevant medical device or IVD medical device-specific standards should also be considered.

While this document includes general labeling principles, it does not include sections that address other possible components of labeling. Individual jurisdictions may have their own regulations or requirements regarding other labeling components.

Advertising and promotional materials are outside the scope of this document.

2.0 References

- GHTF/SG1/N78:2012 *Principles of Conformity Assessment for Medical Devices*
- GHTF/SG1/N055:2009 *Definitions of the Terms Manufacturer, Authorised Representative, Distributor and Importer*
- GHTF/SG1/N046:2008 *Principles of Conformity Assessment for In Vitro Diagnostic (IVD) Medical Devices*
- GHTF/SG1/N071:2012 *Definition of the Terms 'Medical Device' and 'In Vitro Diagnostic (IVD) Medical Device'*
- IMDRF/UDI WG/N7:2013 *UDI Guidance Unique Device Identification (UDI) of Medical Devices*
- IMDRF/GRRP WG/N47:2018 *Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices*
- IMDRF/UDI WG/N7:2013 *UDI Guidance: Unique Device Identification (UDI) of Medical Devices*
- IMDRF/RPS WG/N19:2016 *Common Data Elements for Medical Device Identification*
- GS1 General Specification: http://www.gs1.org/docs/gsmp/barcodes/GS1_General_Specifications.pdf
- Health Industry Business Communications Council (HIBCC)UDI and Labeling Resource Center: http://www.hibcc.org/udi-resources/
- International Council for Commonality in Blood Banking Automation (ICCBBA) - Technical Specification

https://www.iccbba.org/tech-library/iccbba-documents/technical-specification

Standards

- ISO 639-1:2002 *Codes for the Representation of Names of Languages – Part 1: Alpha-2 Code*
- ISO 3864-1:2011 *Graphical Symbols. Safety Colours and Safety Signs. Part 1: Design Principles for Safety Signs and Safety Markings*
- ISO 15223-1:2016 *Medical Devices -- Symbols to be Used with Medical Device Labels, Labeling and Information to be Supplied -- Part 1: General Requirements*
- ISO 14971:2007 *Medical Devices – Application of Risk Management to Medical Devices*
- IEC 62366-1:2015 *Medical Devices – Part 1: Application of the Usability Engineering Process to Medical Devices*
- ISO/IEC 646:1991 *Information Technology - ISO 7-bit Coded Character Set for Information Interchange*
- ISO/IEC 15415:2011 *Information Technology - Automatic Identification and Data Capture Techniques. Bar Code Symbol Print Quality Test Specification - Two-Dimensional Symbols*
- ISO/IEC 15416:2016 *Automatic Identification and Data Capture Techniques - Bar code Print Quality Test Specification - Linear Symbols*
- ISO/IEC 15426-1:2006 *Information Technology- Automatic Identification and Data Capture Techniques - Bar Code Verifier Conformance Specification — Part 1: Linear Symbols*
- ISO/IEC 15426-2:2015 *Information Technology-Automatic Identification and Data Capture Techniques - Bar code verifier conformance specification — Part 2: Two-Dimensional Symbols*
- ISO/IEC 15459-2:2015 *Information technology - Automatic Identification and Data Capture Techniques - Unique Identification, Part 2: Registration Procedures*
- ISO/IEC 15459-4:2014 *Information Technology - Automatic Identification and Data Capture Techniques - Unique Identification, Part 4: Individual Products and Product Packages*
- ISO/IEC 15459-6:2014 *Information Technology - Automatic Identification and Data Capture Techniques - Unique Identification, Part 6: Groupings*
- ISO/IEC 16022:2006 *Information Technology- Automatic Identification and Data Capture Techniques-Data Matrix Bar Code Symbology Specification*
- ISO/IEC TR 29158:2011 *Information technology - Automatic identification and data capture techniques - Direct Part Mark (DPM) Quality Guideline*
- ISO/IEC 18000-6:2013 *Information Technology -- Radio Frequency Identification for Item Management -- Part 6: Parameters for Air Interface Communications at 860 MHz to 960 MHz*
- ISO 18113:2009 *In vitro diagnostic medical devices -- Information supplied by the manufacturer (labelling)*

3.0 Definitions

3.1 *Accessory:* An article intended specifically by its manufacturer to be used together with a particular medical device or IVD medical device to enable or assist that medical device or IVD medical device to be used in accordance with its intended use. (GHTF/SG1/N71: 2012)

3.2 *Analytical Performance of an IVD Medical Device:* The ability of an IVD medical device to detect or measure a particular analyte. (GHTF/SG5/N6:2012)

3.3 *Catalog number*: The value given by the manufacturer to identify the specific medical device as it relates to its form/fit, function and process (i.e., manufacturing processes requiring differentiation for the end user). (Adapted from IMDRF/RPS WG/N19:2016)

3.4 *Conformity Assessment Body (CAB):* A body other than a Regulatory Authority engaged in determining whether the relevant requirements in technical regulations or standards are fulfilled. (IMDRF/GRRP WG/N040:2017)

3.5 *Contraindication:* Labeling elements that describe situations, such as patient populations, medical reasons, or clinical conditions, in which the device should not be used because the risk of use clearly outweighs any possible benefit.

3.6 *Clinical Investigation:* Any systematic investigation or study in or on one or more human subjects, undertaken to assess the safety and/or performance of a medical device. Explanation: This term is synonymous with 'clinical trial' and 'clinical study'. (GHTF/ SG5/N1R8:2007)

3.7 *Clinical Performance:* The ability of a medical device to achieve its intended purpose as claimed by the manufacturer. (GHTF/SG5/N1R8:2007)

3.8 *Clinical Performance of an IVD Medical Device:* The ability of an IVD medical device to yield results that are correlated with a particular clinical condition/physiological state in accordance with target population and intended user. (Adapted from GHTF/SG5/N6:2012)

NOTE 1: Clinical performance can include diagnostic sensitivity and diagnostic specificity based on the known clinical/physiological state of the individual, and negative and positive predictive values based on the prevalence of the disease.

3.9 *Device Identifier (UDI-DI)*: The UDI-DI is a unique numeric or alphanumeric code specific to a model of medical device and that is also used as the "access key" to information stored in a Unique Device Identification Database (UDID). Examples of the UDI-DI include GS1 GTIN (Global Trade Item Number), HIBCC-UPN (Universal Product Number), ISBT 128-PPIC (Processor Product Identification Code). (GHTF UDI WG/N7: 2013).

3.10 *Electronic Labeling:* Any form of electronically accessible information supplied by the manufacturer related to a medical device or IVD medical device.

3.11 *Expected Lifetime/Expected Service Life:* Time-period specified by the manufacturer during which the medical device or IVD medical device is expected to maintain safe and effective use.

NOTE 1: The expected lifetime can be determined by stability.

NOTE 2: Maintenance, repairs, or upgrades (e.g. safety or cybersecurity modifications) can be necessary during the expected lifetime.

3.12 *Expiry Date/Expiration Date:* Upper limit of the time interval during which the safety and performance characteristics of a material stored under specified conditions can be assured.

NOTE 1: This also applies to medical devices whose physical, chemical or functional properties are maintained during a specified and known period, such as for capital equipment.

NOTE 2: Expiry dates are assigned to IVD reagents, calibrators, control materials and other components by the manufacturer, based on experimentally determined stability properties.

(Adapted from ISO 18113-1:2009)

3.13 *Hazard:* Potential source of harm. (ISO/IEC Guide 51:2014)

3.14 *Indications for Use:* A general description of the disease or condition the medical device or IVD medical device will diagnose, treat, prevent, cure, or mitigate, including a description of the patient population for which the medical device or IVD medical device is intended.

3.15 *Information for Safety*: Information provided to the user or responsible organization that is used as a risk control measure or disclosure of a residual risk.

NOTE 1: Examples can include warnings or precautions, instructions in the use of a medical device or IVD medical device to prevent use error or avoid a hazardous situation, or explanation of a safety feature of a medical device or IVD medical device.

3.16 *Intended Use / Intended Purpose*: The objective intent regarding the use of a product, process or service as reflected in the specifications, instructions and information provided by the manufacturer. (Adapted from GHTF/SG1/N77:2012)

NOTE: The intended use can include the indications for use.

3.17 *Instructions for Use:* General and technical information provided by the manufacturer to inform the device user of the medical device or IVD medical device's intended purpose and proper use and of any contraindications, warnings, or precautions to be taken. It is provided by the manufacturer to support and assist the device users in its safe and appropriate use. (GHTF/SG1/N70:2011)

NOTE 1: Instructions for use can also be referred to as "package insert."

3.18 *In Vitro Diagnostic (IVD) Medical Device:* 'In Vitro Diagnostic (IVD) medical device' means a medical device, whether used alone or in combination, intended by the manufacturer for the in-vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes.

NOTE 1: IVD medical devices include reagents, calibrators, control materials, specimen receptacles, software, and related instruments or apparatus or other articles and are used, for example, for the following test purposes: diagnosis, aid to diagnosis, screening, monitoring, predisposition, prognosis, prediction, determination of physiological status.

NOTE 2: In some jurisdictions, certain IVD medical devices may be covered by other regulations.

(GHTF/SG1/N071:2012)

3.19 *Label:* Written, printed, or graphic information either appearing on the medical device itself, or on the packaging of each unit, or on the packaging of multiple devices. (GHTF/SG1/N70:2011)

NOTE: The definition above refers to the human readable label.

3.20 *Labeling:* The 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. (GHTF/SG1/N70:2011)

NOTE 1: Labeling can also be referred to as "information supplied by the manufacturer."

NOTE 2: Labeling can be in printed or electronic format and may either physically accompany the medical device or direct the user to where the labeling information can be accessed (such as through a website).

3.21 *Lay User:* Individual who does not have formal training in a relevant field or discipline. (Adapted from GHTF/SG1/N045:2008)

NOTE 1: Principles for lay person(s) may also apply to self-testing for a medical device or IVD medical device.

NOTE 2: For an IVD medical device used outside of a laboratory setting, the user of the IVD medical device will be considered a lay user.

NOTE 3: For an IVD medical device for self-collection/self-testing, a self-tester is considered a lay user.

3.22 *Lot number*: A distinctive set of numbers and/or letters that specifically identifies a medical device or IVD medical device batch and permits its manufacturing, packaging, labeling and distribution history to be traced. (Adapted from ISO 18113-1: 2011)

NOTE 1: This can also be referred to as the lot code, batch number, or batch code.

3.23 *Manufacturer:* "Manufacturer" means any natural or legal person[2] with responsibility for design and/or manufacture of a medical device with the intention of making the medical device available for use, under their name; whether or not such a medical device is designed and/or manufactured by that person themselves or on their behalf by another person(s). (GHTF/SG1/N055:2009)

NOTE 1: This 'natural or legal person' has ultimate legal responsibility for ensuring compliance with all applicable regulatory requirements for the medical device 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 within that jurisdiction.

NOTE 2: The manufacturer's responsibilities are described in other 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.

NOTE 3: 'Design and/or manufacture', as referred to in the above definition, may include specification development, production, fabrication, assembly, processing, packaging, repackaging, labeling, relabeling, sterilization, installation, or remanufacturing of a medical device; or putting a collection of devices, and possibly other products, together for a medical purpose.

NOTE 4: 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.

NOTE 5: 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.

NOTE 6: An authorised 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 labeling, is not considered a manufacturer.

[2] The term "person" that appears here and in the other definitions of this document, includes legal entities such as a corporation, a partnership or an association.

NOTE 7: To the extent that an accessory is subject to the regulatory requirements of a medical device[3], the person responsible for the design and/or manufacture of that accessory is considered to be a manufacturer.

3.24 *Medical Device*: Any 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 of the specific medical purpose(s) of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury,
- investigation, replacement, modification, or support of the anatomy, or of a physiological process,
- supporting or sustaining life,
- control of conception,
- cleaning, disinfection or sterilization of medical devices,
- providing information 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, in or on the human body, but which may be assisted in its intended function by such means.

Note: Products which 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.

(Adapted from GHTF/SG1/N071:2012)

NOTE 1: For clarification purposes, in certain regulatory jurisdictions, devices for cosmetic/aesthetic purposes are also considered medical devices.

NOTE 2: For clarification purposes, in certain regulatory jurisdictions, the commerce of devices incorporating human tissues is not allowed.

[3] See GHTF/SG1/N29 *Information Document Concerning the Definition of the Term "Medical Device"*

3.25 *Packaging*: Product to be used for the containment, protection, handling, delivery, storage, transport and presentation of goods, from raw materials to processed goods, from the producer to the user or consumer, including processor, assembler or other intermediary. (ISO 21067-1:2016)

3.26 *Patient:* An individual under the care of a healthcare provider who may benefit from the action of a medical device. A patient may also be a user of a medical device.

3.27 *Performance:* The ability of a medical device to achieve its intended purpose as stated by the manufacturer. Performance may include both clinical and technical aspects.

3.28 *Performance of an IVD Medical Device:* The ability of an IVD medical device to achieve its intended use/intended purpose as claimed by the manufacturer. The performance of an IVD medical device consists of the analytical and, where applicable, the clinical performance supporting the intended use of the IVD medical device. (GHTF/SG5/N6:2012)

3.29 *Precaution:* Information regarding any special care users should exercise for the safe and effective use of the device or IVD device, or to avoid damage to the device or IVD medical device that could occur as a result of use, including misuse (Adapted from ISO 18113-1).

3.30 *Production Identifier (UDI-PI)*: The Production Identifier is a numeric or alphanumeric code that identifies the unit of device production. The different types of Production Identifier(s) include serial number, lot/batch number, Software as a Medical Device (SaMD) version and manufacturing and/or expiration date. (GHTF UDI WG/N7: 2013)

3.31 *Regulatory Authority (RA):* A government body or other entity that exercises a legal right to control the use or sale of medical devices within its jurisdiction, and that may take enforcement action to ensure that medical products marketed within its jurisdiction comply with legal requirements. (IMDRF/GRRP WG/N040:2017)

3.32 *Risk:* Combination of the probability of occurrence of harm and the severity of that harm. (ISO/IEC Guide 51:2014)

3.33 *Safety:* Freedom from unacceptable risk. (ISO/IEC Guide 51:2014)

3.34 *Self-Testing:* A medical device or IVD medical device used by a lay user who is responsible for collecting the data or specimen, by themselves and on themselves, relying solely on the instructions provided by the manufacturer. This use can also include performing the test and interpreting the results by themselves and on themselves.

3.35 *Shelf-Life*: Period of time until the expiry date during which a medical device in its original packaging maintains its stability under the storage conditions specified by the manufacturer.

NOTE: Stability (3.38) and expiry date (3.12) are related concepts

(Adapted from ISO 18113-1:2009)

3.36 *Single Use Device*: A medical device or IVD medical device that is intended to be used on an individual patient during a single procedure and then disposed of. It is not intended to be reprocessed and used again.

3.37 *Stability*: Ability of a medical device and IVD medical device to maintain its safety and performance characteristics within the manufacturer's specifications over a specified period of time.

NOTE 1: Stability applies to

- Sterile and non-sterile medical devices whose physical, chemical or functional properties may be altered or compromised over a stated time interval;
- IVD reagents, calibrators and controls, when stored, transported and used in the conditions specified by the manufacturer,
- Reconstituted lyophilized materials, working solutions and material removed from sealed containers, when prepared, used and stored according to the manufacturer's instructions for use,
- Measuring instruments or measuring systems after calibration.

NOTE 2 Stability of an IVD reagent or measuring system is normally quantified with respect to time and specified conditions

- In terms of the duration of a time interval over which a measured property changes by a stated amount or
- In terms of the change of a property under specified conditions.

(Adapted from ISO 18113-1:2009)

3.38 *Unique Device Identifier:* The UDI is a series of numeric or alphanumeric characters that is created through a globally accepted device identification and coding standard. It allows the unambiguous identification of a specific model or version of medical device on the market along with its associated production information. The UDI is comprised of the UDI-DI and UDI-PI. (Adapted from GHTF UDI WG/N7: 2013)

NOTE 1: The word "Unique" does not imply serialization of individual production units.

3.39 *User:* The person, professional or lay, who uses a medical device. The patient may be that user. (GHTF/SG1/N070:2011)

3.40 *Warning:* Information describing a situation for which there is a foreseeable serious hazard with the use of the device.

4.0 Principles for Medical Device and IVD Medical Device Identification

Medical devices and IVD medical devices may be identifiable in multiple ways, as described below. The ways in which identifier information should be included in the labeling are discussed in subsequent sections of this document.

4.1 The medical device or IVD medical device should be identifiable via a method that allows differentiation from other products of the same type, such as through the use of a brand or trade name.

4.2 A medical device or IVD medical device should be identified with a catalogue number. A combination of medical devices or IVD medical devices or accessories may also be so identified. Each catalogue number should only involve one defined product specification.

4.3 If required by the relevant authority, a medical device or IVD medical device should be identified with Unique Device Identifier (UDI) and the UDI-DI should be linked to a catalogue number in the UDID. UDI should be issued under a system operated by an accredited issuing agency/entity and conform to relevant international standards.

For guidance on the information to be incorporated within the label for UDI purposes, refer to the IMDRF guidance document on this subject[4].

5.0 General Labeling Principles for Medical Devices and IVD Medical Devices

This section describes the general principles that apply equally to all medical devices and IVD medical devices. The primary purpose of labeling is to identify the medical device or IVD medical device and its manufacturer, and provide essential information about its safety, performance and appropriate use to the user, professional or lay, or other person, as appropriate. Such information may appear on the device itself, on packaging or as instructions for use. These documents should be developed and evaluated using risk management principles[5] and usability engineering processes[6]. Certain jurisdictions may require the inclusion of additional information.

The following principles are recommended.

[4] For additional guidance refer to IMDRF/UDI WG/N7 FINAL:2013 *Unique Device Identification (UDI) of Medical Devices*

[5] For additional guidance refer to ISO 14971: 2007 *Medical Devices – Application of Risk Management to Medical Devices*

[6] For additional guidance refer to IEC 62366-1:2015 *Medical Devices – Part 1: Application of the Usability Engineering Process to Medical Devices*

5.1 Labeling

5.1.1 The medium, format, content, legibility, and location of the labeling should be appropriate to the particular medical device or IVD medical device, its intended purpose, and intended users to ensure safe and appropriate use, taking into consideration the following:

- user education;
- user training;
- any special needs of the persons for whom the device is intended; and
- the location and environment in which the device can be used.

5.1.2 Country-specific requirements for the content of the labeling should be kept to the minimum and, where they currently exist, eliminated as the opportunity arises.

5.1.3 Depending on the requirements of the RA having jurisdiction, labeling may be provided in one or more language(s). Languages may be identified using the plain text name of the language or a language code[7].

5.1.4 The use of internationally recognised symbols[8] in labeling should be encouraged provided that device safety is not compromised by a lack of understanding on the part of the user. Where the meaning of the symbol is not obvious to the device user, e.g. for a newly introduced symbol, an explanation should be provided within the instructions for use.

5.1.5 Residual risks that are to be communicated to the user and/or other persons should be included in the labeling.

5.1.6 If required by the RA having jurisdiction, the labeling should include a summary of the performance studies and clinical investigations used to demonstrate conformance with regulatory review principles and that demonstrate the safety and clinical performance of the medical device or IVD medical device for its intended use. This summary should include but may not be limited to a summary of the investigation, clinical performance and outcome data, clinical safety information, and a summary of the clinical benefit. If not contained in the instructions for use, a reference should be included as to where such information may be accessed.

[7] For additional guidance refer to ISO 639-1:2002.

[8] Such as those found in ISO 15223-1:2016 *Medical devices -- Symbols to be used with medical device labels, labeling and information to be supplied -- Part 1: General requirements*

5.2 Label

The label should contain the following, which may appear on the medical device or IVD medical device itself, on the packaging of each unit, or on the packaging of multiple medical devices or IVD medical devices. It is important to note that medical device and IVD medical device kits may include individual reagents, articles, or medical devices that may be made available as separate medical devices or IVD medical devices. In this situation, those individual medical devices and IVD medical devices contained in the kit should comply with the label content principles in this section.

5.2.1 The information required on the label should be provided on the device itself. If this is not practicable or appropriate (for example, contact lenses, bone cement, software, etc.), some or all the information may appear on the packaging for each unit, and/or on the packaging of multiple devices. If UDI is required by the RA having jurisdiction, it should be on the label and on all device packages, and, for reprocessed devices intended to be used more than once, it should be provided on the device itself.

5.2.2 The label on the outside packaging should include any special handling measures or permissible environmental conditions for storage and transport of the medical device or IVD medical device. Where premature unpacking of a medical device or IVD medical device or its parts could result in an unacceptable risk, the packaging should be marked appropriately. If UDI is required by the RA having jurisdiction, the UDI-DI record should include the storage condition.

5.2.3 Where relevant, the label on the packaging should include an indication of the net quantity of contents, expressed in terms of weight or volume (including volume after reconstitution), numerical count, or any combination of these or other terms which accurately reflects the contents of the package. If UDI is required by the RA having jurisdiction, the net quantity should be included in the UDID.

5.2.4 The label should contain the brand or trade name of the medical device or IVD medical device. If UDI is required by the RA having jurisdiction, the brand or trade name should also appear in the UDID.

5.2.5 The details strictly necessary for a user to identify the device and its use, e.g. 'cardiac ablation catheter 10 French / 20 cms' or 'paediatric thermometer' or 'Blood Glucose Meter' or 'HIV-1/HIV-2 Antibody Test'. If UDI is required by the RA having jurisdiction, this information should match and be stored in the appropriate field(s) of the UDID.

5.2.6 The label should be provided in a human-readable format but may be supplemented by machine-readable forms, such as radio-frequency identification (RFID) or bar codes [9]. If UDI is required by the RA having jurisdiction, please follow the requirements of the appropriate UDI issuing agency/entity.

5.2.7 In jurisdictions that have implemented a UDI system, the UDI of the medical device or IVD medical device in human-readable format and machine readable form should be on the label of the medical device or IVD medical device. There should be only one machine readable format on the label; if there are multiple, there should be a clear indication to anyone relying on capture/use of this format throughout distribution and use, including the provider of care, which machine readable format to scan when and for what purpose.

[9] For additional guidance refer to IMDRF/UDI WG/N7 FINAL:2013 *Unique Device Identification (UDI) of Medical Devices*

5.2.8 If a catalogue number is used to identify the medical device or IVD medical device, the label should include this catalogue number. In jurisdictions that have implemented a UDI system, a UDI should be used to identify the device and the catalogue number should be linked in the UDID to a UDI.

5.2.9 The label should contain the name and full address of the manufacturer or authorized representative in a format that is recognizable and allows the location of the manufacturer to be established. A full address should contain information related to the physical location such as street/road, number/floor/house, city, state/region, postal code, country, etc. An abbreviated version of the address may be sufficient on the label if the device is accompanied by instructions for use that provide a full address. If UDI is required by the RA having jurisdiction, the name of the manufacturer should also appear in the UDID.

5.2.10 For imported medical devices or IVD medical devices, the label should contain the name and postal address of the authorised representative (such as the importer or distributor) in the importing country/jurisdiction, if such information is required by the RA having jurisdiction. This information may be added by the authorised representative within the country of import, rather than be provided by the manufacturer, in which case, the additional information should not obscure any of the manufacturer's labels.

5.2.11 If the label includes symbols and safety-related identification colors[10], the marking should be described and explained, where necessary.

5.2.12 The label should include the batch code, batch number, lot code, lot number, serial number, control number, or version number of the medical device or IVD medical device, as appropriate. If UDI is required by the RA having jurisdiction, the UDI would include the appropriate UDI-PI.

5.2.13 The label should include an unambiguous indication of the date until when the device may be used safely, expressed at least as the year and month (e.g. on devices supplied sterile or single use disposable devices), where this is relevant. Where there is no indication of the date until when it may be used safely, the year of manufacture should be provided. This year of manufacture may be included as part of the batch or serial number, provided the date is clearly identifiable. If UDI is required by the RA having jurisdiction, the UDI would include the expiry date and manufacturer date in the UDI-PI.

5.2.14 If the medical device or IVD medical device is supplied sterile, the label should include an indication of the device's sterile state and, where applicable, the sterilization method. If UDI is required by the RA having jurisdiction, the sterilization information on the label would be included in the UDI-DI record of the UDID.

[10] For additional guidance see ISO 3864-1:2011 *Graphical Symbols. Safety Colours and Safety Signs. Part 1: Design Principles for Safety Signs and Safety Markings*

5.2.15 Where appropriate, the label should state that the medical device or IVD medical device contains or incorporates a medicinal or biological substance, e.g. heparin-coated catheter or drug-coated stent.

5.2.16 The label should include any warnings or precautions to be taken that need to be brought to the immediate attention of the user of the medical device or IVD medical device as relevant, and to any other person where appropriate (e.g. 'CAUTION – HOT SURFACE' or 'THIS PRODUCT CONTAINS LATEX' or 'CONTAINS POTENTIALLY INFECTIOUS MATERIAL'). This information may be kept to a minimum, in which case more detailed information should appear in the instructions for use.

5.2.17 If the medical device or IVD medical device is intended by the manufacturer for single-use only, reuse on a single patient, and/or reuse on more than one patient, the label should indicate this.[11] If UDI is required by the RA having jurisdiction, the UDI-DI record should indicate the sterility information in the UDID.

5.2.18 If the medical device or IVD medical device is intended only for premarket clinical investigational, premarket performance evaluation, non-clinical research, or presentation or demonstration purposes, the label should indicate this specific use. In these situations, some of the principles listed in this document may not apply.

5.3 Instructions for Use

5.3.1 Instructions for use should be written in terms readily understood by the intended user and, where appropriate, supplemented with drawings and diagrams near the corresponding text. Some medical devices or IVD medical devices may include separate information for the professional user and the lay person.

5.3.2 Where the manufacturer supplies multiple medical devices or IVD medical devices to a single user and/or location, it may be sufficient to provide only a single copy of the instructions for use. In these circumstances, the manufacturer should provide further copies upon request or make the electronic format available.

5.3.3 Instructions for use may not be needed or may be abbreviated for certain medical devices or IVD medical devices if they can be used safely and as intended by the manufacturer without any such instructions for use. Justification for any omission should be described in the manufacturer's risk analysis for the medical device or IVD medical device.

5.3.4 Instructions for use may be provided to the user either in paper or non-paper format (e.g. electronic). They may be supplied by various means either with the medical

[11] According to Note 5 of GHTF/SG1/N055:2009 *Definitions of the Terms Manufacturer, Authorised Representative, Distributor and Importer,* 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. As a consequence, a reprocessor of a single use device would be subject to the same requirements as those applicable to a manufacturer.

device or IVD medical device or separate from it. Examples of other means are information displayed on a screen incorporated into the medical device or IVD medical device, information downloaded from the manufacturer's web site using the internet, and machine-readable sources. The means chosen should be appropriate for, and accessible to, the anticipated user population. Any updates to the IFU need to be consistent across paper and electronic formats whether they are retrospective or batch specific.

5.3.5 If the manufacturer has a website, the instructions for use may also be made available on that website. In this situation, the medical device or IVD medical device packaging should include a means for the user to easily access the electronic instructions for use via inclusion of a web address or other information. For jurisdictions that have a UDID and capture the link, the link should be recorded in the UDID.

5.3.6 Where instructions for use are provided on a medium other than paper, the manufacturer should ensure the user has information on how to:

- view the instructions for use;
- access the correct version of the instructions for use; and
- obtain a paper version of the instructions for use.

NOTE: The RA having jurisdiction may set the conditions under which such non-paper format should be provided to guarantee a high level of protection of health. Those conditions may specify the types of medical devices or IVD medical devices that can use a non-paper format and the requirements the manufacturer needs to respect, such as, that the manufacturer should upon request provide a paper version of the instructions for use free of charge.

5.3.7 The instructions for use should contain the name or trade name of the medical device or IVD medical device.

5.3.8 The instructions for use should include a description of the medical device or IVD medical device. This description should include but may not be limited to a summary of the design of the medical device or IVD medical device and how it is intended to be used.

5.3.9 The instructions for use should contain the name and address of the manufacturer in a format that is recognizable and allows the location of the manufacturer to be established (e.g., street/road, number/floor/house, city, state/region, postal code, country, etc.), together with contact information (e.g., a telephone number and/or fax number and/or website address) to obtain technical assistance.

5.3.10 The instructions for use should state the medical device's or IVD medical device's intended use/purpose, including the intended user (e.g. professional or lay person), as appropriate.

5.3.11 The instructions for use should state the performance of the medical device or analytical performance of the IVD medical device claimed by the manufacturer.

5.3.12 The instructions for use should include any specifications the user requires to use, process, and maintain the device appropriately. For example, if the medical device or IVD medical device performs any measurements, the instructions for use should include the claimed limits of accuracy.

5.3.13 The instructions for use should include information that allows the user and/or patient to be sufficiently informed of any warnings, precautions, measures to be taken and limitations of use regarding the medical device or IVD medical device. This information should cover, where appropriate:

a) warnings, precautions and/or measures to be taken in the event of malfunction of the medical device or IVD medical device or changes in its performance that may affect safety;

b) warnings, precautions and/or measures to be taken in regards to the exposure to reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, or temperature;

c) warnings, precautions and/or measures to be taken in regards to the risks of interference posed by the reasonably foreseeable presence of the medical device or IVD medical device during specific diagnostic investigations, evaluations, therapeutic treatment or use (e.g. electromagnetic interference emitted by the device affecting other equipment);

d) precautions related to materials incorporated into the device that are carcinogenic, mutagenic or toxic, or could result in sensitisation or allergic reaction of the patient or user.

e) precautions related to potentially infectious material that is included in a medical device or IVD medical device.

f) warnings, precautions and/or limitations related to the medicinal substance or biological material that is incorporated into or included with the medical device or IVD medical device.

5.3.14 The instructions for use should include any recommended quality control procedures to be taken to verify that the medical device or IVD medical device performs as intended, including the following if applicable:

a) the procedure for using the available controls;

b) instructions recommending the frequency of use;

c) the limitations of the quality control procedure, clearly delineated;

d) how the user should interpret the quality control procedure results, including a description of whether test results can or cannot be accepted when a quality control procedure fails; and

e) the actions to be taken if there is a failure of any of the controls.

5.3.15 If the medical device or IVD medical device incorporates or includes a medicinal substance and/or material of biological origin, the instructions for use should identify that substance or material, and list any warnings, precautions and/or limitations related to this substance.

5.3.16 The instructions for use should include any relevant residual risks, contraindications, and any expected and foreseeable side effects, including information to be conveyed to the patient in this regard.

5.3.17 The instructions for use should include the details of any preparatory treatment or handling of the medical device or IVD medical device before it is ready for use (e.g., sterilization, identification of other necessary equipment not provided with the medical device or IVD medical device, final assembly, reconstitution, calibration, etc).

5.3.18 The instructions for use should include any requirements for special facilities (e.g. clean room environment), or special training, or particular qualifications of the user and/or third parties.

5.3.19 The instructions for use should include any information needed to verify whether the medical device or IVD medical device is properly installed and is ready to perform safely and as intended by the manufacturer, including (where relevant) details of the nature, and frequency, of preventative and regular maintenance, and of any preparatory cleaning or disinfection; identification of any consumable components and how to replace them; information on any necessary calibration to ensure that the device operates properly and safely during its intended life span; and methods of mitigating the risks encountered by persons involved in installing, calibrating or servicing medical devices or IVD medical devices.

5.3.20 The instructions for use should include an indication of any special storage (e.g. temperature, light, humidity, etc.) and/or handling conditions that apply.

5.3.21 The instructions for use should include any warnings or precautions to be taken related to the disposal of the medical device or IVD medical device, its accessories and the consumables used with it, if any. This information should cover, where appropriate:

a) infection or microbial hazards (e.g. explants, needles or surgical equipment contaminated with potentially infectious substances of human origin);

b) environmental hazards (e.g. batteries or materials that emit potentially hazardous levels of radiation);

c) physical hazards (e.g. from sharps).

5.3.22 If the medical device or IVD medical device is supplied sterile, the instructions for use should include instructions to be followed in the event of the sterile packaging being damaged or unintentionally opened before use.

5.3.23 If the medical device or IVD medical device is supplied non-sterile with the intention that it is sterilized before use, the instructions for use should include appropriate instructions for sterilization and should also include instructions for cleaning the device prior to sterilization, if cleaning is required.

5.3.24 If the medical device or IVD medical device is reusable, the instructions for use should include information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of re-sterilization. Information should be provided to identify when the device should no longer be reused, e.g. signs of material degradation or the maximum number of allowable reuses.

5.3.25 For medical devices or IVD medical devices intended for use together with other medical devices, IVD medical devices, and/or general purpose equipment, the instructions for use should include information sufficient to identify such devices or equipment, in order to obtain a safe combination, and/or information on any known restrictions to combinations of medical devices or IVD medical devices and equipment.

5.3.26 If the medical device or IVD medical device emits hazardous, or potentially hazardous levels of radiation for medical purposes, the instructions for use should include detailed information as to the nature, type and where appropriate, the intensity and distribution of the emitted radiation; and/or the means of protecting the patient, user, or third party from unintended radiation during use of the device.

5.3.27 The instructions for use should state the date of issue or latest revision of the instructions for use and, where appropriate, an identification number.

6.0 General Labeling Principles for Medical Devices other than IVD Medical Devices

6.1 Label

6.1.1 If the medical device is for use by a single individual and has been manufactured according to a written prescription or pattern (i.e. it is patient-specific), the label should indicate this fact. For jurisdictions that have a UDID and capture whether a medical device or IVD medical device is only available via prescription from a medical professional, this designation should be indicated in the UDI-DI record of the UDID.

6.2 Instructions for Use

6.2.1 If the medical device administers medicinal or biological products, the instructions for use should indicate any limitations or incompatibility in the choice of substances to be delivered.

7.0 General Labeling Principles for IVD Medical Devices

7.1 Label

7.1.1 The label should include an indication that the device is for in vitro diagnostic use. If UDI is required by the RA having jurisdiction, the label should include the UDI.

7.2 Instructions for Use

7.2.1 The description of the intended use should include the following, where applicable:

- what the device measures or detects;
- its function (e.g. screening, monitoring, diagnosis or aid to diagnosis, prognosis, prediction, companion diagnostics);
- the specific disorder, condition or risk factor of interest that it is intended to detect, define or differentiate;
- whether it is automated or not;
- what the device reports (e.g., qualitative test, semi-quantitative, quantitative test);
- the type of specimen(s) (e.g. serum, plasma, whole blood, tissue biopsy, urine) required including the specimen source(s) (e.g. capillary whole blood from arm), matrix (e.g. EDTA tube), time (e.g. 8 hours after injury) and collection method (e.g. self-collected urine); and

- target population (on whom the IVD medical device is used).

7.2.2 The instructions for use should include a statement of the test principle(s), such as the general biological, chemical, microbiological, immunochemical and other principles on which the IVD medical device is based. Proprietary information need not be disclosed, but provide enough detail to allow the user to understand how the IVD medical device is able to carry out its function.

7.2.3 The instructions for use should include a description of the reagent, calibrators and controls and any limitation upon their use (e.g. suitable for a dedicated instrument only).

NOTE: IVD medical device kits include individual reagents and articles that may be made available as separate IVD medical devices. In this situation, where appropriate, these IVD medical devices should comply with the instructions for use content in this section.

7.2.4 The instructions for use should include a list of materials provided and a list of special materials required but not provided.

7.2.5 The instructions for use should include a description of in-use stability. This may include the storage conditions prior to opening and shelf-life following the first opening of the primary container, together with the storage conditions and stability of working solutions, where this is relevant.

7.2.6 The instructions for use should list the conditions for collection, shipping, handling, and preparation of the specimen.

7.2.7 Where relevant, the instructions for use should include the metrological traceability of values assigned to calibrators and trueness-control materials, including identification of applicable reference materials and/or reference measurement procedures of higher order.

7.2.8 The instructions for use should describe the assay procedure including calculations and interpretation of results, any additional software or reference database required, and where relevant, if any confirmatory testing should be considered.

7.2.9 The instructions for use should list the analytical performance characteristics, such as precision, sensitivity, specificity, and accuracy (which is a combination of trueness and precision).

7.2.10 Where relevant, the instructions for use should list the clinical performance characteristics (e.g. diagnostic sensitivity, diagnostic specificity, positive predictive value, negative predictive value, likelihood ratio, expected values in normal and affected populations, etc.).

7.2.11 Where relevant, the instructions for use should include the reference intervals in normal and affected populations.

766 **7.2.12** The instructions for use should include information on any interfering substances
767 or limitations (e.g. visual evidence of hyperlipidaemia or haemolysis, age of
768 specimen/sample) that may affect the performance of the assay.

769 **7.2.13** Where relevant, the instructions for use should include a bibliography.

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8.0 Labeling Principles for Software as a Medical Device

8.1 Software that is incorporated into a medical device or IVD medical device or that is intended for use as software as a medical device (SaMD) should be identified with a unique identifier, such as version, revision level or date of release/issue and should be available to the intended user.

8.2 For software embedded into a medical device or IVD medical device, the identification need not be on the outside of the medical device or IVD medical device.

8.3 For SaMD without a physical form or packaging, the label may be available electronically. In this situation, the medical device should incorporate a means for the user to easily access the electronic label via inclusion of a web address or other information.

9.0 Labeling Principles for Medical Devices and IVD Medical Devices Intended for Use by Lay Persons

9.1 The information and instructions provided by the manufacturer should be easy for the intended lay user to understand and apply, in order to correctly interpret the result provided by the device.

9.2 Instructions for use intended to be used principally by lay users should be available in a format appropriate and accessible to the lay user.

9.3 Some devices may include separate information for the professional user and the lay person, e.g. a simplified job aid for lay persons. This information should agree with the instructions for use, and should state the clearly the version it relates to where applicable. It should be written at a level consistent with the education, training and any special needs of its intended readers

9.4 The language of the intended use statement may be simplified in an instructions for use used by lay persons (including self-testing), provided key messages remain. In addition, instructions for use for home use medical devices or self-testing IVD medical devices may omit some of the recommended elements, provided this does not affect safety or performance. Justification for any omission should be described in the manufacturer's risk analysis for the product.

9.5 Interpretation of results should include pictorial representations of all possible test results (including when a device has failed to provide a valid result) for medical devices or IVD medical devices that give a visual readout, where possible.

9.6 For medical devices or IVD medical devices intended for use by lay persons, the instructions for use should clearly and concisely describe the circumstances when the user should consult with a healthcare professional.

9.7 For IVD medical devices intended for self-testing, the instructions for use should clearly state this.

10.0 Labeling Principles for Information Intended for the Patient

The following principles describe general considerations for information intended to be provided to the patient before or after use of the medical device. Note that the principles below may only apply to certain types of products, and depend on the particular medical device and RA having jurisdiction as to what principles may apply.

10.1 Information that is specifically intended for the patient should be provided with the medical device.

10.2 If the information intended for the patient includes an implant card, the card should clearly identify the medical device or, if UDI is required by the RA having jurisdiction, the UDI of the implant should be identifiable prior to implantation, be available to be scanned, parsed into DI + PI and the DI should be used to pull data from the relevant UDID into the patient's health record. In addition, the data recorded on the implant card should include the following:

a) The name or trade name of the medical device. If UDI is required by the RA having jurisdiction, obtained from UDI-DI linked to UDID.

b) The details strictly necessary for a user to identify the medical device and its use, e.g. 'transcatheter heart valve' or 'synthetic hernia mesh'. If UDI is required by the RA having jurisdiction, obtained from UDI-DI linked to UDID.

c) The information should be provided in a human-readable format but may be supplemented by machine-readable forms, such as bar codes. If UDI is required by the RA having jurisdiction, human readable and machine-readable format should following requirements of accredited issuing agency/entity.

d) If a catalogue number is used to identify the medical device, the number should be included. If UDI is required by the RA having jurisdiction, obtained from UDI-DI linked to this field in UDID.

e) The card should contain the name and full address of the manufacturer or authorized representative in a format that is recognizable and allows the location of the manufacturer to be established. A full address should contain information related to the physical location such as street/road, number/floor/house, city, state/region, postal code, country, etc. An abbreviated version of the address may be sufficient if the device information leaflet provides a full address. If UDI is required by the r RA having jurisdiction, obtained from UDI-DI linked to this field in UDID.

f) The card and/or data recorded in the health record should include the batch code, batch number, lot code, lot number, serial number, or control number of the medical device, such that it is uniquely identified. If UDI is required by the RA having jurisdiction, obtained from parsing the UDI into UDI-DI + relevant UDI-PI.

10.3 If the information intended for the patient includes an information leaflet, the information in the leaflet should be written in a way that is readily understood by patients. In addition, the leaflet should include the information mentioned in the following table, as well as information established in specific standards, as applicable. Note that the following table is only a suggestion of the structure and content of the patient information leaflet.

Item	Information to be included
1	(a) the UDI-DI (b) the name of the medical device; and (c) the model of the medical device.
2	(a) the intended purpose; and (b) the kind of patient on whom the medical device is intended to be used.
3	Any special operating instructions for the use of the medical device.
4	(a) the intended performance of the medical device; and (b) any undesirable side effects that could be caused by use of the medical device.
5	Warnings about any residual risks that may remain due to any shortcomings of the protection measures adopted.
6	(a) warnings about risks that could arise from the interaction of the medical device with other equipment; and (b) precautions and other measures that, because of those risks, should be taken by the patient or a health professional. Example 1: The risk of electrical interference from electro-surgical medical devices. Example 2: The risk of magnetic field interference from magnetic resonance imaging medical devices.
7	(a) the nature and frequency of regular or preventative examination, monitoring or maintenance that should be undertaken; and (b) symptoms that could indicate that the medical device is malfunctioning; and (c) precautions and other measures that should be taken by the patient if the performance of the medical device changes or the patient experiences any of the symptoms mentioned in paragraph (b); and (d) the expected lifetime; and (e) anything that could shorten or lengthen the expected lifetime; and (f) precautions and other measures that should be taken at, or near, the end of the expected lifetime; and (g) other circumstances in which the patient should contact a health professional in relation to the operation of the medical device.

Item	Information to be included
8	(a) the materials and substances included in the medical device; and (b) any manufacturing residuals that could pose a risk to the patient.
9	(a) a notice that any serious incident that occurs in relation to the medical device should be reported to the manufacturer.

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