



IMDRF International Medical
Device Regulators Forum

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

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A handwritten signature in blue ink, appearing to be 'Elena M. Astapenko'.

Elena M. Astapenko, IMDRF Chair

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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.

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Introduction

The purpose of this IMDRF guidance is to provide globally harmonized labelling principles for medical devices, including in vitro diagnostic (IVD) medical devices, and support the IMDRF Essential Principles of Safety and Performance¹. Specifically, this document provides guidance on the content of the label, instructions for use, and information intended for the patient in order to support the safe and effective use of medical devices and IVD medical devices by their intended 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 labelling requirements in various jurisdictions. Country-specific requirements for the content of the labelling should be kept to the minimum and, where they currently exist, eliminated as the opportunity arises.

Labelling serves to identify a device and its manufacturer, and to communicate information on safety, use, and performance. In some jurisdictions, “labelling” is referred to as “information supplied by the manufacturer”. Labelling 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 and IVD medical devices, both professional and lay persons, as appropriate, and for relevant third parties.

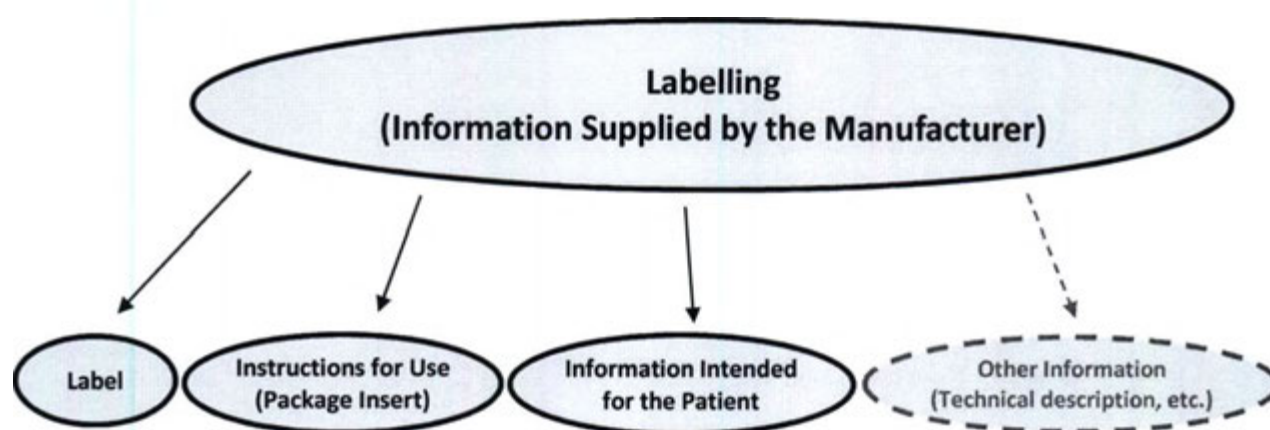


Figure 1. Elements of Medical Device and IVD Medical Device Labelling

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

¹ See IMDRF/GRRP WG/N47 FINAL:2018 *Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices*

This guidance document describes the general labelling 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 labelling principles that are globally harmonized. Depending on the RA having jurisdiction and the particular medical device or IVD medical device, there may be additional labelling requirements that may need to be met.

1.0 Scope

This document applies to all medical devices, including IVD medical devices, and is intended to specify the general content and format of medical device and IVD medical device labelling in paper or electronic format. This document provides general labelling principles, including specific sections on the label, instructions for use, 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 labelling principles, it does not include sections that address other possible elements of labelling. Advertising and promotional materials may be considered elements of labelling by some RAs having jurisdiction, but they are outside the scope of this document. Individual jurisdictions may have their own regulations or requirements regarding other labelling elements or advertising and promotional materials.

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/RPS WG/N19:2016 *Common Data Elements for Medical Device Identification*
- IMDRF/SaMD WG/N10 FINAL:2013 *Software as a Medical Device (SaMD): Key Definitions*
- IMDRF/PMD WG/N49 FINAL:2018 *Definitions for Personalized Medical Devices*
- GS1 General Specification:
http://www.gs1.org/docs/gsmf/barcodes/GS1_General_Specifications.pdf

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- Health Industry Business Communications Council (HIBCC)UDI and Labeling Resource Center: <http://www.hibcc.org/udi-resources/>

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 8601:2004 *Data Elements and Interchange Formats – Information Interchange – Representation of Dates and Times.*
- ISO 13485:2016 *Medical devices -- Quality management systems -- Requirements for regulatory purposes*
- ISO 15223-1:2016 *Medical Devices -- Symbols to be Used with Medical Device Labels, Labelling and Information to be Supplied -- Part 1: General Requirements*
- ISO 14971:2012 *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 *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)
- 3.2 *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)
- 3.3 *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/N40:2017)
- 3.4 *Contraindication*: Labelling 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.
- 3.5 *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. This term is synonymous with 'clinical trial' and 'clinical study'. (GHTF/ SG5/N1R8:2007)
- 3.6 *Clinical Performance*: The ability of a medical device to achieve its intended purpose as claimed by the manufacturer. (GHTF/SG5/N1R8:2007)
- 3.7 *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: Clinical performance can include but is not necessarily limited to 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.

- 3.8 *Electronic Labelling*: Any form of labelling content provided in an electronically accessible form supplied by the manufacturer related to a medical device or IVD medical device.
- 3.9 *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 or by other methods.

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

- 3.10** *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)

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

- 3.12** *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.

- 3.13** *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: 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.

- 3.14** *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. (Modified from GHTF/SG1/N77:2012)

NOTE 1: The intended use/intended purpose are also part of promotional or sales materials or statements, although these materials lie outside the scope of this document.

NOTE 2: The intended use can include the indications for use.

- 3.15** *Instructions for Use*: General and technical information provided by the manufacturer to inform the 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: Instructions for use can also be referred to as "package insert."

3.16 *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/N71:2012)

3.17 *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.

3.18 *Labelling:* 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: Labelling can also be referred to as “information supplied by the manufacturer.”

NOTE 2: Labelling can be in printed or electronic format and may either physically accompany the medical device or direct the user to where the labelling information can be accessed (such as through a website), as permitted by regulatory jurisdiction.

3.19 *Lay User:* Individual who does not have formal training in a relevant field or discipline.
(Adapted from GHTF/SG1/N046:2008)

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

NOTE 2: For an IVD medical device for self-collection or self-testing, a self-collector or self-tester is considered a lay user.

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

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

3.21 *Manufacturer:* “Manufacturer” means any natural or legal person² 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 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 and IMDRF 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, labelling, relabelling, 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 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.

NOTE 7: To the extent that an accessory is subject to the regulatory requirements of a medical device³, the person responsible for the design and/or manufacture of that accessory is considered to be a manufacturer.

3.22 *Medical Device:* Any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by

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.

³ See GHTF/SG1/N29 *Information Document Concerning the Definition of the Term “Medical Device”*

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:

- cleaning and 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/N71:2012)

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.

- 3.23** *Model*: The name and/or number used to represent one medical device, or a family of medical devices to group many variations that have shared characteristics. (IMDRF/RPS WG/N19:2016)
- 3.24** *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)
- 3.25** *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.

- 3.26 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.
- 3.27 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)
- 3.28 Personalized Medical Device:** a generic term to describe any of the types of devices that are intended for a particular individual, which could be either a custom-made, patient-matched, or adaptable medical device. (IMDRF/PMD WG/N49)
- 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 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/N40:2017)
- 3.31 Risk:** Combination of the probability of occurrence of harm and the severity of that harm. (ISO/IEC Guide 51:2014)
- 3.32 Residual Risk:** Risk remaining after risk reduction measures have been implemented. (ISO/IEC Guide 51:2014).
- 3.33 Safety:** Freedom from unacceptable risk. (ISO/IEC Guide 51:2014)
- 3.34 Serial Number:** A unique sequence of numbers or letters in a series used to identify an individual unit of a medical device (IMDRF/RPS WG/N19:2016).
- 3.35 Self-Testing:** Use of a medical device or IVD medical device 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.

NOTE: Self-testing may include a third-party caregiver

(Modified from IMDRF/GRRP WG/N47:2018)

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

NOTE: Stability (3.38) and expiry date (3.10) are related concepts

(Adapted from ISO 18113-1:2009)

- 3.37** *Single Use Device*: A medical device or IVD medical device that is intended to be used on an individual patient during or for a single procedure and then disposed of. It is not intended to be reprocessed and used again.
- 3.38** *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)

- 3.39** *Unique Device Identifier (UDI)*: 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 medical device on the market. The UDI is comprised of the UDI-DI and UDI-PI. (IMDRF/UDI WG/N7: 2013)

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

- 3.40** *User*: The person, professional or lay, who uses a medical device. The patient may be that user. (GHTF/SG1/N070:2011)
- 3.41** *Warning*: Statement that alerts users about a situation that, if not avoided, could result in hazards or other serious adverse consequences from the use of a medical device or an IVD medical device. (Adapted from ISO 18113-1:2009)

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 labelling are

discussed in subsequent sections of this document.

- 4.1 The medical device or IVD medical device should be identified through the use of a brand or trade name that allows differentiation from other products of the same or similar type.
- 4.2 A medical device or IVD medical device, or a combination of medical devices or IVD medical devices or accessories, should be distinguishable from other devices via use of a catalog number, or another method that allows identification of the device model and its distinguishing characteristics. Each catalog number should only involve one defined product specification.
- 4.3 If required by the RA having jurisdiction, a medical device or IVD medical device should be identified with a Unique Device Identifier (UDI) in human- and machine-readable form. For implantable devices, the UDI should be identifiable and able to be scanned prior to implantation. For further guidance on the information to be incorporated within the label for UDI purposes, the content of the information to be captured in the UDI, the inclusion of UDI information in the UDI database, and the linkage of UDI with clinical, industry, and government databases, refer to the IMDRF guidance document on this subject⁴.

5.0 General Labelling 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 labelling 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 or other relevant persons. 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 principles⁵ and usability engineering processes⁶. Certain jurisdictions may require the inclusion of additional information or the use of specific formatting.

The following principles are recommended.

5.1 Labelling

- 5.1.1 The medium, format, content, legibility, and location of the labelling should be appropriate to the particular medical device or IVD medical device, its intended

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*

purpose, and intended users to ensure safe and appropriate use, taking into consideration the following:

- user knowledge;
- 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 Labelling should be subject to document (version) control principles.

5.1.3 Depending on the requirements of the RA having jurisdiction, labelling may be provided in one or more language(s). Languages may be identified using the plain text name of the language or a language code⁷.

5.1.4 The use of internationally recognized symbols⁸ in labelling is 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 user, e.g. for a newly introduced symbol, an explanation should be provided within the labelling.

5.1.5 Residual risks that are to be communicated to the user and/or other persons should be included in the labelling and are considered to be information for safety.

5.1.6 If required by the RA having jurisdiction, the labelling 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, and should be presented in such a way as to accurately reflect the safety and performance of the medical device or IVD medical device. If not contained in the instructions for use, a reference should be included as to where such information may be accessed.

5.1.7 The labelling should not contain any language regarding the manufacturer's liability in the case of damage or injury resulting from any use or malfunction of the medical device or IVD medical device that contradicts the laws or regulations in the jurisdiction of use.

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, labelling and information to be supplied -- Part 1: General requirements (ISO 7000, IEC 60417)*

- 5.1.8** The labelling should not contain any disclaimers related to the safety and performance of the medical device or IVD medical device for its intended purpose that are incompatible with the laws or regulations in the jurisdiction of use, or the obligations of the manufacturer to design and manufacture a product that is safe and performs as intended throughout its expected lifetime.

5.2 Label

The label should contain the following information, 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 in a label on the device itself. If this is not practicable or appropriate (for example, for small-size devices, 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 follow the requirements of the appropriate UDI-issuing agency/entity. The UDI 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 (e.g., upper and lower temperature limits, light, humidity) 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 label should be marked appropriately. The use of non-specific temperature or humidity indications that are open to interpretation, or which may vary according to geographic location is to be avoided unless further qualification is included (e.g., “store at room temperature, i.e.15-25°C” or “store in a cool place below 15°C, do not freeze”).
- 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.
- 5.2.4** The label should contain the brand or trade name of the medical device or IVD medical device.
- 5.2.5** The label should contain the details necessary for a user to identify the device and its use, e.g. ‘cardiac ablation catheter 10 French / 20 cm’ or ‘pediatric thermometer’

or 'blood glucose meter' or 'HIV-1/HIV-2 antibody test'.

- 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 codes⁹.
- 5.2.7** 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.
- 5.2.8** If a catalog number is used to identify the medical device or IVD medical device, the label should include this catalog number.
- 5.2.9** The label 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. The 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 providing the full address on the label is not practical, and if the device includes instructions for use that provide a full address. If permitted by the RA having jurisdiction, this principle may be fulfilled with a URL on the label that when accessed contains the full address of the manufacturer in a format that is recognizable and allows the location of the manufacturer to be established.
- 5.2.10** If an authorized representative is acting on behalf of the manufacturer in the country/jurisdiction, the label should also contain the address of the authorized representative, if such information is required by the RA having jurisdiction. This information may be added by the authorized 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. If permitted by the RA having jurisdiction, this principle may be fulfilled with a URL on the label that when accessed contains the full address of the authorized representative in a format that is recognizable and allows the location of the authorized representative to be established.
- 5.2.11** For imported medical devices or IVD medical devices, the label should contain the name and physical address of the importer or distributor within the importing country/jurisdiction, if such information is required by the RA having jurisdiction. This information may be added by the importer or distributor 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.

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

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- 5.2.12** If the label includes symbols and safety-related identification colors¹⁰, the marking should be explained, where necessary.
- 5.2.13** 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.
- 5.2.14** The label should include an unambiguous indication of the date, such as the expiry date, after which the medical device or IVD medical device cannot be used safely, where this is relevant (e.g. on devices supplied sterile or single-use disposable devices). Ideally, this date should be expressed as the full year, month, and day because this format provides the least ambiguity. The label should also include the date of manufacture, if required by the RA having jurisdiction. In this case, the date of manufacture may be included as part of the batch or serial number, provided the date is clearly identifiable.
- 5.2.15** If the medical device or IVD medical device is supplied sterile, the label should include an indication that the device is provided in a sterile state and, where applicable, the sterilization method.
- 5.2.16** 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. If required by the RA having jurisdiction, the label should also include the quantity, proportion or strength of that substance (e.g. contains 10mg/ml sodium hyaluronate; gentamicin (2%)) if the substance will be in direct contact with the patient.
- 5.2.17** 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, such as through the use of symbols, in which case more detailed information should appear in the instructions for use.
- 5.2.18** The label should indicate if the medical device or IVD medical device is intended by the manufacturer for single-use only or reuse on a single patient. The label may indicate reuse in more than one patient if warranted. If the medical device or IVD medical device is reusable and its reusability is limited, the label should indicate these limitations (e.g., maximum number of allowable reuses).
- 5.2.19** The label should indicate if the medical device or IVD medical device is intended only for premarket clinical investigation, premarket performance evaluation, non-clinical research, or presentation or demonstration purposes. In these situations,

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*

some of the principles listed in this document may not apply.

Labels should be durable and legible for at least the lifetime of the medical device or IVD medical device.

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 instructions for use available in an electronic format.
- 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 in paper or electronic format or both, as permitted by the RA having jurisdiction. They may be supplied by various means either with the medical 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 website, and machine-readable sources. The means chosen should be appropriate for the use environment and accessible to the anticipated user population. Any updates to the instructions for use 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 appropriate electronic instructions for use via inclusion of a web address or other information.
- 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 for when the electronic instructions for use should be provided to guarantee a high level of safety. These conditions may specify the types of medical devices or IVD medical devices that can use electronic instructions for use and the requirements the manufacturer needs to follow. For example, the RA may specify that the manufacturer should upon request provide a paper version 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 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, together with contact information (e.g., telephone number, fax number, website or email address) to obtain technical assistance, if such information is required by the RA having jurisdiction.
- 5.3.10 The instructions for use should state the medical device's or IVD medical device's intended use/purpose, including the indications for use, intended user (e.g. professional or lay person), and intended use environment, as appropriate.
- 5.3.11 The instructions for use should state the performance of the medical device or 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 functionality that may affect safety or performance;
 - b) warnings, precautions and/or measures to be taken in regard 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 regard 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 potentially carcinogenic, mutagenic or toxic, or could result in sensitization or allergic reaction for the patient or user; and

e) precautions related to potentially infectious material that is included in a 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 procedures for using any available controls;

b) instructions recommending the frequency of use;

c) the limitations of the quality control procedure;

d) how the user should interpret the quality control procedure results, including a description of whether test results can or cannot be accepted; 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 or biological substance, the instructions for use should identify that substance or material, and list any warnings, precautions and/or limitations related to this substance. If required by the RA having jurisdiction, the instructions for use should also include the quantity, proportion or strength of that substance if the substance will be in direct contact with the patient.

5.3.16 The instructions for use should include information describing the purpose and interpretation of any indicators (e.g., humidity, temperature) provided within the packaging, and what steps to take based on the indicator results.

5.3.17 The instructions for use should identify information for safety including any relevant residual risks, contraindications, and any expected and foreseeable adverse events, including information to be conveyed to the patient in this regard.

5.3.18 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).

5.3.19 The instructions for use should include any requirements for special facilities (e.g. sterile field or clean room environment), or special training, or particular

qualifications of the user and/or third parties.

- 5.3.20** The instructions for use should contain any information needed to verify that the medical device or IVD medical device is properly installed and ready to perform safely and as intended by the manufacturer, including when applicable:
- a) details and frequency of preventive and regular maintenance;
 - b) cleaning and disinfection information
 - c) identification of consumable components and how to replace them;
 - d) necessary calibration information; and
 - e) methods for mitigating risks encountered during cleaning, installation, calibration or servicing.
- 5.3.21** The instructions for use should include any special handling measures or permissible environmental conditions (e.g., upper and lower temperature limits, light, humidity) for storage and transport of the medical device or IVD medical device. The use of non-specific temperature or humidity indications that are open to interpretation, or which may vary according to geographic location is to be avoided unless further qualification is included.
- 5.3.22** 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 and its accessories. This also includes any consumables that require special disposal as a result of being used with the medical device or IVD medical device. 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); and
 - c) physical hazards (e.g. from sharps).
- 5.3.23** 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.
- 5.3.24** The instructions for use should include any instructions to be followed in the event of the packaging being damaged or unintentionally opened before use, or if the packaging is exposed to environmental conditions outside of those specified.
- 5.3.25** 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 any instructions for cleaning the device prior to sterilization.

- 5.3.26** 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).
- 5.3.27** 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 sufficient information 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.
- 5.3.28** 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, distribution, and recommended dose of the emitted radiation; and/or the means of protecting the patient, user, or third party from unintended radiation during use of the device.
- 5.3.29** 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 Labelling Principles for Medical Devices other than IVD Medical Devices

In addition to the principles outlined in Section 5.0, medical devices should also meet the following labelling principles.

6.1 Label

- 6.1.1** The label should indicate if the medical device is for use by a single individual and has been manufactured according to a written prescription or pattern (e.g., it is a personalized medical device).

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 incompatibilities in the choice of substances to be delivered.

7.0 General Labelling Principles for IVD Medical Devices

In addition to the principles outlined in Section 5.0, IVD medical devices should also meet the following labelling principles.

7.1 Label

7.1.1 The label should state that the IVD medical device is for in vitro diagnostic use.

7.2 Instructions for Use

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

- a) what the IVD medical device measures or detects;
- b) its function (e.g. screening, monitoring, diagnosis or aid to diagnosis, prognosis, prediction, companion diagnostic);
- c) the specific disorder, condition or risk factor of interest that it is intended to detect, define or differentiate;
- d) whether or not it includes automated components or is intended to be used with automated instruments;
- e) what the IVD medical device reports (e.g., qualitative test, semi-quantitative, quantitative test);
- f) 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
- g) 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 should 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 and the amount 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 any 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 included and excluded conditions for collection, shipping, handling, and preparation of the specimen.
- 7.2.7 Where relevant, the instructions for use should include the 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, accuracy, sensitivity, and specificity.
- 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).
- 7.2.11 Where relevant, the instructions for use should include the reference intervals in normal and affected populations.
- 7.2.12 The instructions for use should include information on any interfering substances or limitations (e.g. visual evidence of hyperlipidemia or hemolysis, age of specimen/sample) that may affect the performance of the assay.
- 7.2.13 Where relevant, the instructions for use should include a bibliography or references section.

8.0 Labelling Principles for Medical Devices Containing Software or 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 an identifier, such as version, revision level or date of build release/issue. The unique

identifier should be accessible to the intended user, unless the medical device does not have a wired or wireless electronic interface.

- 8.2 For software incorporated into a medical device or IVD medical device, the identifier does not need to 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 the software itself or via inclusion of a web address or other means.

9.0 Labelling 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 allow the intended lay user to understand and apply, in order to correctly interpret the result provided by the device or to confirm that the device is operating or has operated as intended.
- 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 clearly the version it relates to. 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 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 applicable.
- 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 Instructions for use should clearly state if an IVD medical device is intended for self-testing. Self-testing may include the involvement of a third-party caregiver.

10.0 Labelling Principles for Information Intended for the Patient

The following principles are not related to the use of a medical device or IVD medical device by a lay person, but instead describe general considerations for information intended to be provided to the patient before or after use of the medical device or IVD medical device by a professional.

Not all medical devices or IVD medical devices include information to be provided to the patient. The need for such information and the applicability of the principles below depend on the RA having jurisdiction and the type of medical device, including implantable devices in certain regulatory jurisdictions.

- 10.1** Information that is specifically intended for the patient should be provided with the medical device or IVD medical device. Depending on the device, the user population and the RA jurisdiction, it may be appropriate for this information to be available electronically. In this situation, the medical device or IVD medical device should include a means for the patient to easily access the electronic information via inclusion of a web address or other information.
- 10.2** Information identifying the device 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, UDI should be included.
- 10.3** If the information intended for the patient includes an implant card, the card should be in a durable format and should include the following:
 - a) identification of the medical device, including the brand or trade name and the device type or use, e.g. ‘transcatheter heart valve’ or ‘synthetic hernia mesh’;
 - b) identification of the device model;
 - c) the catalog number;
 - d) the number used to uniquely identify the medical device, such as the lot number, serial number, or UDI; and
 - e) the name and address of the manufacturer and any authorized representative or importer in a format that is recognizable and allows their location 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.
- 10.4** If the information intended for the patient includes an informational brochure, the information in the brochure should be written in a way that is readily understood by patients. In addition, the brochure should include the following information, as well as any other information relevant to the device or recommended in specific standards, as applicable:
 - a) the name of the medical device;

- b) the model of the medical device;
- c) the intended use, including the intended purpose and patient population;
- d) any special operating instructions for the use of the medical device;
- e) a description of the medical device, its mechanism of action, and its expected performance;
- f) any adverse event the patient may potentially experience due to the medical device;
- g) warnings about any relevant residual risks;
- h) warnings about risks that could arise from the interaction of the medical device with other equipment, and precautions and other measures that should be taken by the patient or a health professional because of these risks;

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.

- i) the nature and frequency of regular or preventive examination, monitoring, or maintenance of the medical device that should be undertaken;
- j) the nature and frequency of any follow-up with healthcare professionals to be performed by the patient;
- k) signs that could indicate that the medical device is malfunctioning;
- l) 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 signs mentioned in item (k);
- m) the expected lifetime of the medical device, and any factors that could affect it;
- n) precautions and other measures that should be taken at, or near, the end of the expected lifetime;
- o) information about the materials and substances, including manufacturing residuals, in the medical device that could pose a risk to the patient;
- p) contact information for the manufacturer;
- q) circumstances in which the patient should contact a health professional; and
- r) guidance regarding whom the patient should contact in the case of any symptoms of an adverse event or a problem with the device.