HEALTH SCIENCES AUTHORITY

REGULATORY GUIDANCE

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MEDICAL DEVICE GUIDANCE

GN-23: Guidance on Labelling for Medical Devices

Revision 1

HSA
Health Sciences Authority

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PREFACE

This document is intended to provide general guidance. Although we have tried to ensure that the information contained here is accurate, we do not, however, warrant its accuracy or completeness. The Health Sciences Authority (HSA) accepts no liability for any errors or omissions in this document, or for any action/decision taken or not taken as a result of using this document. The information contained in this document should not be a substitute for professional advice from your own professional and healthcare advisors.

REVISION HISTORY

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**Where applicable, changes and updates made in each document revision are annotated with or within the arrow symbol "►". Deletions may not be shown*

1. INTRODUCTION

1.1. Purpose

This document is meant to provide general guidance on labelling for medical devices. Where appropriate, the labelling should also meet the requirements of any other applicable regulatory controls in Singapore.

1.2. Background

Labelling serves to communicate safety and performance related information to users of medical devices and/or patients as well as to identify individual devices. Such information may appear on the device itself, on the packaging, as instructions for use or in a patient information leaflet.

1.3. Scope

This document applies to all medical devices, including in vitro diagnostic medical devices.

1.4. Definitions

Definitions that do not indicate they are set out in the Health Products Act (*Act*) or Health Products (Medical Devices) Regulations 2010 (*Regulations*) are intended as guidance in this document. These definitions are not taken verbatim from the above legislation and should not be used in any legal context. These definitions are meant to provide guidance in layman terms.

CLINICAL INVESTIGATION: Any designed and planned systematic study undertaken on human subjects to verify the safety or performance of a specific medical device

LABEL *(as set out in the Act)*: in relation to a health product or an active ingredient, means any written, printed or graphic representation that appears on or is attached to the health product or active ingredient or any part of its packaging, and includes any informational sheet or leaflet that accompanies the health product or active ingredient when it is being supplied.

LAY PERSON: An individual who does not have formal training in a relevant field or discipline.

INSTRUCTIONS FOR USE: Information provided by the product owner to inform the device user of the medical device's intended purpose and proper use and of any precautions to be taken.

INTENDED PURPOSE/INTENDED USE *(as set out in the Regulations)*: in relation to a medical device or its process or service, means the objective intended use or purpose, as reflected in the specifications, instructions and information provided by the product owner of the medical device.

PERFORMANCE EVALUATION: A review of the performance of a medical device based upon data already available, scientific literature and, where appropriate, laboratory, animal or clinical investigations.

PRODUCT OWNER *(as set out in the Regulations)*: in relation to a health product, means a person who —

(a) supplies the health product under his own name, or under any trade mark, design, trade name or other name or mark owned or controlled by him; and

(b) is responsible for designing, manufacturing, assembling, processing, labelling, packaging, refurbishing or modifying the health product, or for assigning to it a purpose, whether those tasks are performed by him or on his behalf

REFURBISHED MEDICAL DEVICE*:* means a medical device the whole or any part of which has been substantially rebuilt, re-equipped or restored, whether or not using parts from one or more used medical devices of that same kind, so as to create a medical device that can be used for the purpose originally intended by the product owner of the original medical device, and without prejudice to the generality of the foregoing, a refurbishment of a medical device may involve any or all of the following actions:-

(a) stripping the medical device into component parts or sub-assemblies;

(b) checking parts of the medical device for suitability for reuse;

(b) replacing component parts or sub-assemblies of the medical device that are not suitable for reuse;
(d) assembling reclaimed or replacement component parts of the medical device or another medical device;
(e) testing the reassembled medical device against the specifications of the original medical device or, if the product owner of the original medical device has revised those specifications, the revised specifications;
(f) identifying the reassembled medical device as a refurbished medical device.

CUSTOM-MADE *(as set out in the Regulations)*: means a medical device that:-
(a) is made at the request of a qualified practitioner and in accordance with the specifications of the qualified practitioner regarding the design characteristics or construction of the medical device;
(b) is intended to be used only in relation to a particular individual; and
(c) is not adapted from a mass-produced medical device.

SINGLE USE DEVICE: means the medical device 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.

USER: the person, either professional or lay, who uses a medical device. The patient may be the user.

2. LABELLING REQUIREMENTS

2.1. General Guidelines

The labelling for all medical devices should adhere to these general guidelines.

(a) As far as it is practical and appropriate, the information needed to identify and use the device safely should be provided on the device itself. If this is not practicable or appropriate, some or all of the information may appear on the packaging for each unit (primary level of packaging), and/or on the outer packaging of multiple devices that are packaged together (secondary level of packaging). If this is not practicable or appropriate, the information should be set out in the instructions for use (e.g. leaflet, manual, packaging insert).

(b) The medium, format, content, readability and location of labelling should be appropriate to the particular device, its intended purpose and the technical knowledge, experience, education or training of the intended user(s). In particular, instructions for use should be written in terms readily understood by the intended user and, where appropriate, supplemented with drawings and diagrams. Some devices may require separate information for the healthcare professional and the lay user.

(c) Instructions for Use (IFU) may not be needed or may be abbreviated for devices of low or moderate risk if they can be used safely and as intended by the product owner without any such instructions.

(d) Paper versions of all labelling must accompany the product, unless specified otherwise.

(e) For medical device software, user instructions may be supplied in electronic data storage devices (e.g. compact disc, digital video disc, USB flash drive).

(f) For devices that are not sold to the general public, instructions for use may be provided to the user either in paper or non-paper format. They may be supplied by various means either with the medical device or separate from it. Examples are information downloadable from the internet and/or on electronic data storage devices (compact disc, digital video disc, USB flash drive, etc.).

(g) Where instructions for use are provided on a medium other than paper, the product owner should ensure the user has information on how to view the instructions for use, and access the correct version of the instructions for use.

(h) For information downloadable from the internet, the internet web address must be clearly printed on the physical label of the device and displayed in such a manner that highlights to the user its purpose. The product owner should ensure that the electronic label is identical in content to the paper format (where applicable) that is submitted with the product registration application. Users and/or other relevant parties should also have access to a paper version of the instructions for use upon request.
Note: Any changes to the electronic label shall comply with the specified requirements in GN-21 Guidance on Change Notification for Registered Medical Devices.

(i) Residual risks which are required to be communicated to the user and/or other person should be included as limitations, contraindications, precautions or warnings in the labelling.

(j) The use of internationally recognised symbols is encouraged and emphasis should be to ensure that device safety is not compromised by a lack of understanding on the part of the patient or user. Where the meaning of the symbol is likely not obvious to the device user, especially lay person e.g. for a newly introduced symbol, an explanation should be provided.

(k) The essential information presented on the labels should be provided in a human-readable format but may be supplemented by machine-readable formats, such as radio-frequency identification (RFID) or bar codes.

(l) All characters on labelling must be of adequate size and legibly printed.

(m) The product labelling must be in English.

2.2. Content of Labelling

Each medical device shall be accompanied by the information necessary to identify the device and its product owner, and communicate safety and performance related information to the user, or other person, as appropriate.

Unless otherwise specified in the guidance document, such information may appear on the device itself, on the packaging or in the instructions for use, and should be available to the user during use of the device. The extent of information required on the label will depend on the complexity and intended purpose of the device.

2.2.1. General elements of labelling

(a) Name and contact details of the Product Owner (address/phone number/electronic mail address, or a link to access this information directly to obtain technical assistance).

(b) The trade or brand name of the medical device.
Note: This information shall be provided on the device packaging and instructions for use to permit the user to identify the device, and the appropriate instructions for use relating to the device.

(c) Sufficient details for the user to identify the device.
Note: This information shall be provided on the device packaging to permit the user to distinguish the device from other devices/device types.

(d) For devices where these are not obvious, its intended purpose, user and patient population of the device.

(e) An indication of either the batch code/lot number (e.g. on single-use disposable devices or reagents) or the serial number (e.g. on electrically-powered medical devices), to allow appropriate actions to trace and recall the devices.
Note: This information shall be provided on the device packaging.

(f) 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, single-use disposable devices or reagents).
Note: This information shall be provided on the device packaging.

(g) For devices other than those covered by point (f) above, and as appropriate to the type of device, an indication of the date of manufacture. This indication may be included in the batch code, lot number (e.g. non-sterile accessories, reusable handpieces) or serial number (e.g. capital equipment, machines).

(h) An indication of any special storage and/or handling condition that applies, including the storage conditions and shelf life following the first opening of the primary container, together with the storage conditions and stability of working solutions.

(i) Date of issue or latest revision of the instructions for use and, where appropriate, an identification number.

(j) Where the medical device is contained in a package and the contents of the package are not readily apparent, an indication of what the package contains, expressed in terms appropriate to the medical device, such as the size, net weight, length, volume or number of units.

(k) Any special operating instructions for the use of the medical device.

(l) If the device is intended by its product owner to be installed with or connected to other medical devices or equipment, or with dedicated software, information 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 and equipment.

(m) The information needed to verify whether the device is properly installed and can operate correctly and safely, including details of the nature, and frequency of preventative and regular maintenance, any quality control, replacement of consumable components, and calibration needed to ensure that the device operates properly and safely during its intended life.

(n) The performance intended by the product owner and any undesirable side effects.

(o) Specifications that the user requires to use the device appropriately, e.g. if the device has a measuring function, the degree of accuracy the device is designed to achieve.

(p) Any requirement for special facilities, or special training, or particular qualifications of the device user and/or third parties.

(q) For devices intended for use by lay persons, the circumstances when the user should consult with a healthcare professional.

(r) Any contra-indications, warnings, restrictions or precautions that may apply in relation to the use of the medical device.

(s) Any warnings, restrictions or precautions to be taken that need to be brought to the immediate attention of the user of the medical device as relevant, and to any other person where appropriate (e.g. CAUTION –

RADIATION HAZARD) should be provided on the device or on its packaging. This information may be kept to a minimum in which case more detailed information should appear in the instructions for use.

(t) Precautions related to materials incorporated into the device e.g. sensitisation or allergic reaction of the patient or user.

(u) Warnings, precautions and/or measures to be taken in the event of malfunction of the device or changes in its performance.

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

(w) Warnings, precautions and/or measures to be taken in regard to the exposure of the patient or user to reasonably foreseeable environmental conditions, or influences due to all or any of the physical features of the medical device such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, pressure or variations in pressure, temperature, humidity, acceleration.

(x) Warnings or precautions to be taken related to the disposal of the device, its accessories and the consumables used with it, if any. This information should cover any special or unusual risk associated with the disposal of the device, and should include, where appropriate

- infection or microbial hazards (e.g. explants, needles or surgical equipment contaminated with potentially infectious substances of human origin);
- environmental hazards (e.g. batteries or materials that emit potentially hazardous levels of radiation);
- physical hazards (e.g. from sharps).

2.2.2. Medical devices supplied in a sterile state

(a) An indication that the medical device is sterile and where appropriate, the sterilization method.
Note: This information shall be provided on the device packaging.

(b) Information about what to do if the sterile packaging is damaged; and if appropriate, instructions for re-sterilisation of the medical device.

2.2.3. Medical devices supplied in a non-sterile state

(a) Details of any treatment or handling needed before the device can be used (e.g. sterilisation, final assembly, calibration, preparation of reagents and/or control materials).

(b) Where a device is supplied with the intention that it is to be sterilised by the user before use, the instructions for cleaning and sterilisation should be such that, if correctly followed, the device should perform as intended by the product owner and continue to comply with the Essential Principles of Safety and Performance of Medical Devices.

2.2.4. Medical devices intended for single-use only

(a) If the device has been specified by the product owner as intended for single-use only, an indication of that state.

2.2.5. Medical devices intended for reuse

(a) If the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of re-sterilisation. 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.

2.2.6. Custom-made medical devices

(a) If the device is for use by a single individual and has been manufactured according to a written prescription or pattern (i.e. it is custom-made), an indication of that state.

2.2.7. Medical devices intended for clinical investigation or performance evaluation

(a) If the device is intended for use solely under special circumstances (e.g. for use in clinical investigation or clinical research, for in-vitro diagnostic use, for performance evaluation use only), an indication of that situation or circumstance.

2.2.8. Medical devices to be supplied for non-clinical use

(a) If the device is to be supplied for non-clinical use e.g. research, training, presentation or demonstration purposes only, it should be clearly labelled as such.

2.2.9. Refurbished medical devices

(a) If the device is a refurbished device, it must be labelled as "refurbished".

2.2.10. Medical devices incorporating or administering medicinal or biological substance

(a) An indication that the device contains or incorporates a medicinal or biological substance, e.g. heparin coated catheter.

(b) Identification of the medicinal substance or biological material incorporated, or is intended to be incorporated, into the device as an integral part of the device, and warning, precautions and/or limitations related to that substance or material.

(c) If the device administers medicinal or biological products, adequate information regarding any medicinal or biological product(s) that the device is designed to administer, including any limitations or incompatibility in the choice of substances to be delivered.

2.2.11. Implantable medical devices

(a) Information about any risks associated with its implantation.

(b) For active implantable medical devices, the device shall display a code that can be used to identify the type of medical device, the product owner of the medical device, and the year of manufacture of the medical device. The code shall be readable without the need for surgery to the person in whom the medical device is implanted e.g. provision of radio-opaque symbols on the device, with/without further telemetry appropriate to the particular device, to obtain further identification details.

2.2.12. Medical devices intended to emit radiation

(a) Details of the nature, type, the intensity, distribution of this radiation, and the means of protecting the patient and user from unintended radiation during use of the device.

2.2.13. In-vitro diagnostic medical devices

(a) An indication that it is for in vitro diagnostic use.

(b) The IVD medical device's intended purpose, including the following information:-

i. Type of analyte or measurand of the assay.
ii. Whether the test is quantitative or qualitative.
iii. Role of the test in the clinical use e.g. screening, diagnostic or detection, aid to diagnostic, monitoring.

iv. The specific disorder, condition or risk factor of interest that it is intended to detect, define or differentiate;

v. Type of specimen to be used e.g. serum, plasma, whole blood, tissue biopsy, urine)

vi. Patient population the IVDD is to be used in

vii. The intended users (e.g. self-testing by lay person, near-patient by trained personnel or professionals).

viii. The specific name of the instrument required for the assay, if any.

ix. For instruments, the intended use should also include the modes of operation for instruments (e.g., random access, batch, stat, open tube, closed tube, automatic, manual).

(c) Test principle.

(d) Conditions for collection, handling, and preparation of the specimen.

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

(f) 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.

(g) Assay procedure including calculations and interpretation of results, and if any confirmatory testing should be considered.

(h) A list of materials provided and a list of special materials required but not provided.

(i) Any warnings and/or precautions related to potentially infectious material that is included in the IVD medical device.

(j) Recommendations for quality control procedures.

(k) Reference intervals.

(l) In use stability which may include, the storage conditions, and shelf life following the first opening of the primary container, together with the storage conditions and stability of working solutions.

(m) Performance evaluation data including analytical and clinical performance characteristics of the IVD. Data to be presented may include the following information as appropriate for the IVD and its intended use:

- Information on interfering substances or limitations (e.g. visual evidence of hyperlipidaemia or haemolysis, age of specimen/sample) that may affect the performance of the assay.

- Analytical performance characteristics, such as sensitivity, specificity, and accuracy (which is a combination of trueness and precision).

- Clinical performance characteristics, including diagnostic sensitivity and diagnostic specificity.

- Clinical study design (population studies, number of samples, type of sample, matrix, dilution, target concentrations, etc.).

3. REFERENCES

I. GHTF, Label and Instructions for Use for Medical Devices, 16 September, 2011
II. Health Canada, Guidance for the Labelling of Medical Devices, not including in vitro diagnostic devices, 16 July 2015
III. Health Canada, Labelling of In Vitro Diagnostic Devices, 22 April 2016

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