

Technical Reference: TR-005

Date of Issue: 23 Apr. 2010

醫療儀器的規管



Regulation of
Medical Devices

Additional Medical Device Labelling Requirements

Technical Reference: TR-005



中華人民共和國

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1. Purpose

This document, adapted from the GHTF document GHTF/SG1-N43:2005, aims to provide the Local Responsible Persons (LRP) and manufacturers with the guidance on general principles and content requirements for labelling medical devices. The LRP shall ensure that the labelling requirements specified in Section 4 of this document are met for the medical devices listed under the Medical Device Administrative Control System (MDACS).

2. Scope

This document applies to all products that fall within the scope of the MDACS specified in the Guidance Notes GN-01: *Overview of the Medical Device Administrative Control System*.

3. Definitions and Abbreviations

This document shall be read in conjunction with the Guidance Notes GN-00: *Definitions and Abbreviations for Medical Device Administrative System* for the latest definitions and abbreviations of the terms used.

4. Additional Medical Device Labelling Requirements

4.1 General Principles

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 packaging (or as a packaging insert), or as instructions for use:

- 4.1.1 Each device must be accompanied by the information needed to use it safely, taking account of the training and knowledge of the potential users.

- 4.1.2 As far as it is practical and appropriate, the information needed to identify and use the device safely shall be provided on the device itself, and/or on the packaging for each unit, and/or on the packaging of multiple devices. If individual packaging of each unit is not practicable, the information shall be set out in the leaflet, packaging insert or other media supplied with, or applicable to, one or multiple devices.
- 4.1.3 Where the manufacturer supplies multiple devices to a single user and/or location, it may be sufficient and appropriate to provide with them only a single copy of the instructions for use. In these circumstances the device user should have access to further copies upon request.
- 4.1.4 The medium, format, content, readability and location of labelling shall be appropriate to the particular device, its intended purpose and the technical knowledge, experience, education or training of the intended user(s). Some devices may require separate information for the healthcare professional and the lay user.
- 4.1.5 Instructions for use shall be written in terms and languages readily understood by the intended user and, where appropriate, supplemented with drawings and diagrams.
- 4.1.6 Instructions for use shall be provided with the device. However, they may not be needed or may be abbreviated for devices of Class I and Class II if the devices can be used safely and as intended by the manufacturer without any such instructions.
- 4.1.7 Any residual risk identified in the risk analysis should be reflected as contraindications or warnings within the labelling.
- 4.1.8 Labelling may be provided to the user in various media and by several means such as printed documents, through a display screen incorporated into the device, downloaded from the manufacturer's web site using the Internet, magnetic or optical media. Whatever the media or the means, information should be targeted to the anticipated user population. Upon request from the user paper copies of labelling shall be made available.
- 4.1.9 Where appropriate, the information can take the form of symbols or colours, provided 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 or colour is not obvious to the device user, an explanation shall be provided in the documentation supplied with the device.

4.1.10 The languages to be used in the labelling information shall be as follows-

- (i) The contact details of the manufacturers and Local Responsible Persons shall be in both English and Chinese wherever applicable.
- (ii) The instructions for use such as user manuals provided shall be in both Chinese and English. If any one of the two languages is not available, it shall be specified as per the requirements of Special Listing Information in Guidance Notes GN-01.
- (iii) Other labelling information such as maintenance manuals provided shall preferably be in both English and Chinese and shall at least be in one of these two languages.

4.2 Contents of Labelling

4.2.1 In general:

4.2.1.1 The names or trade names and addresses of the manufacturer shall be given in the labelling.

Furthermore, the instructions for use and/or the device itself shall preferably be labelled with the device's Listing Number and LRP information in the same format as specified under Special Listing Information of Guidance Notes GN-01.

4.2.1.2 Sufficient details for the user to identify the device and, where these are not obvious, its intended purpose, user and patient population of the device; also, where relevant, the contents of any packaging.

4.2.1.3 An indication of either the batch code/lot number (e.g. of single-use disposable devices or reagents) or the serial number (e.g. of electrically powered medical devices), where relevant, and to allow appropriate actions to trace and recall the devices.

4.2.1.4 An unambiguous indication of the date until which 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), where this is relevant. Where relevant, the storage conditions and shelf life following the first opening of the primary container, together with the storage conditions and stability of working solutions.

- 4.2.1.5 For devices other than those covered by 4.2.1.4 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 or the serial number.
- 4.2.1.6 Any special storage and/or handling conditions at the appropriate packaging level.
- 4.2.1.7 Any warnings, precautions, limitations or contraindications.
- 4.2.1.8 The performance intended by the manufacturer and, where relevant, any undesirable side effects.
- 4.2.1.9 The information needed to verify whether the device is properly installed and can operate correctly and safely, plus details of the nature, and frequency of preventative and regular maintenance, where relevant any quality control, replacement of consumable components, and calibration needed to ensure that the device operates properly and safely during its intended life.
- 4.2.1.10 Details of any further treatment or handling needed before the device can be used (e.g. sterilization, final assembly, calibration, preparation of reagents and/or control materials, etc.) where relevant.
- 4.2.2 Where applicable:
 - 4.2.2.1 An indication that the device is sterile and necessary instructions in the event of damage to sterile packaging and, where appropriate, description of methods of re-sterilization.
 - 4.2.2.2 An indication that the device has been specified by the manufacturer as intended for single-use only.
 - 4.2.2.3 An indication that 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).
 - 4.2.2.4 An indication that the device is intended for premarket clinical investigation or, for *in vitro* diagnostic medical devices, performance evaluation only.
 - 4.2.2.5 An indication that the device is intended only for presentation or demonstration purposes.

- 4.2.2.6 If the device is to be installed with or connected to other medical devices or equipment, or with dedicated software, in order to operate as required for its intended use, sufficient details of its characteristics to identify the correct devices or equipment to use in order to obtain a safe combination.
- 4.2.2.7 If the device is implantable, information regarding any particular risks in connection with its implantation.
- 4.2.2.8 Information regarding the risks of reciprocal interference posed by the reasonably foreseeable presence of the device during specific investigations, evaluations, treatment or use (e.g. electromagnetic interference from other equipment).
- 4.2.2.9 If the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of re-sterilization and any restriction on the number of reuses. Where a device is supplied with the intention that it is sterilized before use, the instructions for cleaning and sterilization should be such that, if correctly followed, the device will still perform as intended by the manufacturer and comply with the *Essential Principles of Safety and Performance of Medical Devices*.
- 4.2.2.10 If the device is a reprocessed device, additionally the name of the reprocessor, and identification of the device as a reprocessed device.
- 4.2.2.11 If the device emits radiation for medical purposes, details of the nature, type and where appropriate, the intensity and distribution of this radiation.
- 4.2.2.12 Date of issue or latest revision of the instructions for use and, where appropriate, an identification number.
- 4.2.3 The instructions for use should also include, where appropriate, details informing the users and/or patient and allowing the medical staff to brief the patient on any contra-indications, warnings and any precautions to be taken. These details should cover in particular:
- 4.2.3.1 Precautions and/or measures to be taken in the event of changes in the performance, or malfunction, of the device including a contact telephone number, if appropriate.

- 4.2.3.2 Precautions and/or measures to be taken as regards exposure, in reasonably foreseeable environmental conditions, to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, temperature, humidity, acceleration, thermal ignition sources, proximity to other devices, etc.
- 4.2.3.3 If the device administers medicinal products, adequate information regarding any medicinal products which the device in question is designed to administer, including any limitations in the choice of substances to be delivered.
- 4.2.3.4 Any precautions to be taken related to the disposal of the device and/or its accessories (e.g. lancets), to any consumables used with it (e.g. batteries or reagents) or to any potentially infectious substances of human or animal origin.
- 4.2.3.5 Any medicinal substances or biological material incorporated into the device as an integral part of the device.
- 4.2.3.6 Degree of accuracy claimed for devices with a measuring function.
- 4.2.3.7 Any requirement for special facilities, or special training, or particular qualifications of the device user and/or third parties.
- 4.2.3.8 Where relevant, for devices intended for lay persons a statement clearly directing the user not to make any decision of medical relevance without first consulting his or her health care provider.
- 4.2.4 For in vitro diagnostic medical devices, in addition to the information required above, directions/instructions for the proper use of in vitro diagnostic medical devices which may include:
 - 4.2.4.1 Intended use/purpose (e.g. monitoring, screening or diagnostic) including an indication that it is for in vitro diagnostic use.
 - 4.2.4.2 Test principle.
 - 4.2.4.3 Specimen type.

- 4.2.4.4 Conditions for collection, handling and preparation of the specimen.
- 4.2.4.5 Reagent description and any limitation (e.g. use with a dedicated instrument only).
- 4.2.4.6 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.
- 4.2.4.7 Assay procedure including calculations and interpretation of results.
- 4.2.4.8 Information on interfering substances that may affect the performance of the assay.
- 4.2.4.9 Analytical performance characteristics, such as sensitivity, specificity, accuracy (which is a combination of trueness and precision).
- 4.2.4.10 Diagnostic performance characteristics, such as sensitivity and specificity.
- 4.2.4.11 Reference intervals.

5. Enquiries

Enquiries concerning this booklet and the MDACS should be directed to:

Medical Device Control Office,

Department of Health

Facsimile number: 3157 1286

Telephone number: 3107 8484

E-mail address: mdco@dh.gov.hk

Website: <http://www.mdco.gov.hk>

All latest versions of published documents and application forms for MDACS are available at MDCO website.

6. References

- [1] Global Harmonization Task Force. *Labelling for Medical Devices* Final Document SG1-N43:2005

- [2] Department of Health. *Overview of the Medical Device Administrative Control System* Guidance Notes GN-01
- [3] Department of Health. *Definitions and Abbreviations for the Medical Device Administrative Control System* Guidance Notes GN-00