

醫療儀器的規管



Regulation of Medical Devices

Definitions and Abbreviations for the Medical Device Administrative Control System

Guidance Notes: GN-00



中華人民共和國

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1 Introduction

This document provides definitions and abbreviations of some of the terms appeared in Guidance Notes, Technical Reference and Code of Practice documents of the Medical Device Administrative Control System (MDACS) implemented by Medical Device Control Office, Department of Health.

2 Definitions

2.1 Abnormal use means intended act or intended omission of an act by the user or operator of medical device as a result of conduct that is beyond any reasonable means of risk control by the manufacturer. Some examples of abnormal use are provided below:

- Deliberate failure to conduct device checks prior to each use as provided in the device labelling;
- Filter removed and intentionally not replaced despite clear warnings in the device labelling, resulting in particulate contamination and subsequent device failure;
- The labelling for a centrifugal pump clearly indicates that it is intended for use in by-pass operations of less than 6 hours in duration. After considering the pump options, a clinician decides that the pump will be used in pediatric extra-corporeal membrane oxygenation (ECMO) procedures, most of which may last several days. A pump fails due to fatigue cracking and patient bleeds to death; and
- Alarm is intentionally disabled, preventing detection of risk condition.

2.2 Accessory (for IVD) refers to an article which, is intended specifically by its manufacturer to:

- be used together with an IVD medical device to enable that device to be used in accordance with its intended use as an IVD medical device.
- or to augment or extend the capabilities of that device in fulfilment of its intended use as an IVD medical device.

and therefore should be considered an IVD medical device.

2.3 Active device intended for diagnosis see Medical device.

2.4 Active implantable medical device see Medical device.

- 2.5 Active medical device** see Medical device.
- 2.6 Active therapeutic device** see Medical device.
- 2.7 Audit** means a systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.
- 2.8 Body orifice** means any natural opening in the body, as well as the external surface of the eyeball, or any permanent artificial opening, such as a stoma or permanent tracheotomy.
- 2.9 Central circulatory system** means the major internal blood vessels including the following: pulmonary veins, pulmonary arteries, cardiac veins, coronary arteries, carotid arteries (common internal and external), cerebral arteries, brachiocephalic artery, aorta (includes all segments of the aorta), inferior and superior vena cava and common iliac arteries.
- 2.10 Central nervous system** means the brain, meninges and spinal cord.
- 2.11 Clinical investigation** means any designed and planned systematic study in human subjects undertaken to verify the safety and/or performance of a specific device.
- 2.12 Conformity Assessment** means the systematic examination of evidence generated and procedures undertaken by the manufacturer, under requirements established by the MDCO, to determine that a medical device is safe and performs as intended by the manufacturer and, therefore, conforms to the Essential Principles of Safety and Performance of Medical Devices under GN-01.
- 2.13 Conformity Assessment Body (CAB)** means a body recognized by the MDCO to engage in the performance of procedures for determining whether the relevant MDACS requirements are fulfilled.
- 2.14 Conformity Assessment Body Recognition Scheme or CAB Recognition Scheme** means the scheme under which CABs are recognized by the MDCO

2.15 Conformity Assessment Certificate means the certificate issued by the CAB to the manufacturer certifying the successful completion of the conformity assessment conducted in accordance with the MDACS requirements.

2.16 Duration of use includes

- (a) **Long-term use** means “normally intended for continuous use for more than 30 days”.
- (b) **Short-term use** means “normally intended for continuous use for between 60 minutes and 30 days”.
- (c) **Transient use** means “normally intended for continuous use for less than 60 minutes”.

2.17 Essential Principles means Essential Principles of Safety and Performance of Medical Devices as described in the Technical Reference TR-004 Essential Principles of Safety and Performance of Medical Devices.

2.18 Examination means set of operations having the object of determining the value of a property. Note: In the IVD medical device industry and in many laboratories that use IVD medical devices, examination of an analyte in a biological sample is commonly referred to as a test, assay or analysis.

2.19 Harm means physical injury or damage to the health of people or damage to property or the environment.

2.20 Hazard means potential source of harm.

2.21 Immediate danger means a situation where the patient is at risk of either losing life or an important physiological function if no immediate preventative measure is taken.

2.22 Implantable medical device see Medical device.

- 2.23 Importer** means a legal or natural person who brings or causes to be brought into Hong Kong any medical devices falling within the scope of the MDACS¹ for distribution or use in Hong Kong but does not include any person who is employed or engaged by such person to carry such products into Hong Kong.
- 2.24 Instructions for use** mean information provided by the manufacturer to inform the device user of the products proper use and of any precautions to be taken.
- 2.25 Intended use/purpose** means use of a product, process, or service in accordance with the specifications, instructions, and information provided by the manufacturer.
- 2.26 Invasive device** see Medical device.
- 2.27 IVD instrument** means equipment or apparatus intended by the manufacturer to be used as an IVD medical device.
- 2.28 IVD medical device** means a 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. This includes reagents, calibrators, control materials, specimen receptacles, software, and related instruments or apparatus or other articles
- 2.29 IVD medical device for Self-testing** means any IVD medical device intended by the manufacturer for use by lay persons.
- 2.30 Label** means information provided upon the medical device itself. Where physical constraints prevent this happening, this term includes information provided on the packaging of each unit or on the packaging of multiple devices.
- 2.31 Labelling** means written, printed or graphic matter
- affixed to a medical device or any of its containers or wrappers, or,
 - accompanying a medical device,
- related to identification, technical description, and use of the medical device, but excluding shipping documents and the Special Listing Information specified in the Guidance Notes GN-01.

¹ See *Overview of the Medical Device Administrative Control System (Guidance Notes GN-01)*

2.32 Lay person means individual that does not have formal training in a relevant field or discipline.

2.33 Life supporting or life sustaining means a device that is essential to, or that yields information that is essential to, the restoration or continuation of a bodily function important to the continuation of human life.

2.34 Local manufacturer means a manufacturer whose business as a manufacturer of medical devices has either been registered in Hong Kong pursuant to the Business Registration Ordinance (Cap. 310) or is part of a business which has been so registered.

2.35 Long-term use see Duration of use.

2.36 Manufacturer means -

- (a) a natural or legal person with responsibility for the design, manufacture, packaging and labelling of a medical device before it is placed on the market under its own name, regardless of whether these operations are carried out by that person himself or on its behalf by a third party; or
- (b) any other natural or legal person who assembles, packages, processes, fully refurbishes or labels one or more ready-made products or assigns to them their intended purpose as a medical device with a view to their being placed on the market under its own name, apart from a person who assembles or adapts medical devices already on the market to their intended purpose for an individual patient.

2.37 Medical device means any instrument, apparatus, implement, machine, appliance, implant, *in vitro* reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of -

- (a) diagnosis, prevention, monitoring, treatment or alleviation of disease; or
- (b) diagnosis, monitoring, treatment, alleviation of or compensation for an injury; or
- (c) investigation, replacement, modification, or support of the anatomy or of a physiological process; or
- (d) supporting or sustaining life; or
- (e) control of conception; or

- (f) disinfection of medical devices; or
- (g) providing information for medical or diagnostic purposes by means of *in vitro* examination of specimens derived from the human body;
and which does not achieve its primary intended action in or on the human body by pharmacological, immunological, or metabolic means, but which may be assisted in its intended function by such means.

According to the characteristics and nature, medical device can be classified into at least the following different types:

- (i) **Active device intended for diagnosis** means an active medical device, whether used alone or in combination with other medical devices, to supply information for detecting, diagnosing, monitoring or to support in treating physiological conditions, states of health, illnesses or congenital deformities.
- (ii) **Active implantable medical device** means any active medical device, together with any accessories for its proper functioning, which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure.
- (iii) **Active medical device** means a device whose operation depends on a source of electrical energy or any source of power other than that directly generated by the human body or gravity and which acts by converting this energy. Medical devices intended to transmit energy, substances or other elements between an active medical device and the patient, without any significant change, is not considered to be active medical devices.
- (iv) **Active therapeutic device** means an active medical device, whether used alone or in combination with other medical devices, to support, modify, replace or restore biological functions or structures with a view to treatment or alleviation of an illness, injury or handicap.
- (v) **Implantable medical device** means any device, including those that are partially or wholly absorbed which is intended-
 - to be totally introduced into the human body; or
 - to replace an epithelial surface or the surface of the eye,by surgical intervention which is intended to remain in place after the procedure. Any device intended to be partially introduced into the human body through surgical intervention and intended to remain in place after the procedure for at least 30 days is also considered an implantable device.

- (vi) **Invasive device** means a device, which, in whole or in part, penetrates inside the body, either through a body orifice or through the surface of the body.
- (vii) **Surgically invasive device** means an invasive device which penetrates inside the body through the surface of the body, with the aid or in the context of a surgical operation.

2.38 Near patient (testing) means testing performed outside a laboratory environment by a healthcare professional not necessarily a laboratory professional, generally near to, or at the side of, the patient.

2.39 Performance evaluation means review of the performance of a medical device based upon data already available, scientific literature and, where appropriate, laboratory, animal or clinical investigations.

2.40 Place on the market means the first making available in return for payment or free of charge of a medical device other than a device intended for clinical investigation, with a view to distribution and/or use on the market, regardless of whether it is new or fully refurbished.

2.41 Quality Management System (QMS) means the organizational structure, responsibilities, procedures, processes and resources for implementing quality management that complies with the standard ISO 13485.

2.42 Reagent refers to chemical, biological or immunological components, solutions or preparations intended by the manufacturer to be used as IVD medical devices.

2.43 Recognised Standards mean standards deemed to offer the presumption of conformity to specific essential principles of safety and performance. They are either international standards issued by IEC or ISO or equivalent or otherwise national standards in the absence of other relevant international standards.

2.44 Reportable adverse incidents mean events involving a listed medical device and meeting the reporting requirements of the Guidance Notes GN-03.

Note: As a general rule, an incident which involves a listed medical device and which has led to one of the following outcomes is reportable by the LRP -

- (a) death of a patient, user or other person; or

- (b) serious injury of a patient, user or other person; or
- (c) no death or serious injury occurred, but the event might lead to death or serious injury of a patient, user or other person if the event recurs.

Where a serious injury under (b) above is defined as either -

- (i) life threatening illness or injury; or
- (ii) permanent impairment of a body function or permanent damage to a body structure; or
- (iii) a condition necessitating medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure.

The reportability of such incidents is subject to the exemption rules listed in the Guidance Notes GN-03. However, such incidents are still reportable regardless of the exemption criteria if they involve issues of serious public health concern, or if a change in trend (usually an increase in frequency) or pattern is identified among them.

2.45 Reprocessing includes all the steps performed to make a contaminated medical device ready for use with a patient. The steps may include cleaning, functional testing, repackaging, relabelling, disinfection or sterilisation.

2.46 Reusable surgical instrument means instrument intended for surgical use by cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or other surgical procedures, without connection to any active medical device and which are intended by the manufacturer to be reused after appropriate procedures for cleaning and/or sterilisation have been carried out.

2.47 Risk means combination of the probability of occurrence of harm and the severity of that harm.

2.48 Self-testing means testing performed by lay persons.

2.49 Serious injury (also known as serious deterioration in state of health) means either:

- Life threatening illness or injury; or
- Permanent impairment of a body function or permanent damage to a body structure; or

- A condition necessitating medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure.
- 2.50 Serious public health concern** means any incident type, which results in imminent risk of death, serious injury, or serious illness that may require prompt remedial action to prevent significant risk of substantial harm to the public.
- 2.51 Service life of a device** means the time or usage that a device is intended to remain functional after it is manufactured, placed into use, and maintained as specified by the manufacturer.
- 2.52 Short-term use** see **Duration of use**.
- 2.53 Specimen** refers to the discrete portion of a body fluid or tissue or other sample associated with the body taken for examination, study, or analysis of one or more quantity or characteristic to determine the character of the whole.
- 2.54 Specimen receptacle** refers to a device, whether vacuum-type or not, specifically intended by its manufacturer for the primary containment of specimens derived from the human body.
- 2.55 Subcontractors (of a CAB)** mean persons or legal entities who contract with the CAB to carry out part of the CAB's conformity assessment tasks.
- 2.56 Summary Technical Documentation (STED)** means a summary of technical documentation held or submitted for conformity assessment purposes.
- 2.57 Surgically invasive device** see **Medical device**.
- 2.58 Technical Documentation** means the documented evidence, normally an output of the quality management system that demonstrates compliance of a device to the Essential Principles of Safety and Performance of Medical Devices.
- 2.59 The Lists** consist of (a) The List of Medical Devices; (b) The List of Importers; and (c) The List of Local Manufacturers. They list respectively the medical devices, importers and local manufacturers conforming to the requirements of

the MDACS. These lists are maintained by the MDCO, who may decide to include on The Lists any other related information considered appropriate and make them available for inspection by the public.

2.60 To list a device (or local manufacturer, etc.) means to include a device (or local manufacturer, etc.) on The List of Medical Devices (or The List of Local Manufacturers, etc.).

2.61 To delist a device (or local manufacturer, etc.) means to remove a device (or local manufacturer, etc.) from The List of Medical Devices (or The List of Local Manufacturers, etc.).

2.62 Transient use see Duration of use.

2.63 Transmission means the conveyance of disease to a person.

2.64 Transmissible agent means an agent capable of being transmitted to a person, as a communicable, infectious or contagious disease.

2.65 Use error means act or omission of an act that has a different result to that intended by the manufacturer or expected by the operator. Some examples of use error are provided below:

- Operator misinterprets the icon and selects the wrong function;
- Operator fails to detect a dangerous increase in heart rate because the alarm limit is mistakenly set too high and operator is over-reliant on alarm system; and
- Operator cracks catheter connector when tightening.

3 Abbreviations

3.1 AHWP stands for Asian Harmonization Working Party..

3.2 AMDNS stands for Asian Medical Device Nomenclature System.

3.3 CAB stands for Conformity Assessment Body.

3.4 CSDT stands for Common Submission Dossier Template.

- 3.5 GHTF** stands for Global Harmonization Task Force. The founding members of the GHTF are the USA, the EU, Canada, Australia, and Japan.
- 3.6 GMDN** stands for Global Medical Device Nomenclature.
- 3.7 IVD** stands for In Vitro Diagnostic.
- 3.8 IVDMD** stands for In Vitro Diagnostic Medical Device.
- 3.9 LRP** stands for Local Responsible Person.
- 3.10 MDACS** stands for Medical Device Administrative Control System.
- 3.11 MDCO** stands for Medical Device Control Office, Department of Health.
- 3.12 QMS** stands for Quality Management System.
- 3.13 STED** stands for Summary Technical Document.
- 3.14 UMDNS** stands for Universal Medical Device Nomenclature System.

4 Enquiries

Enquiries concerning this booklet and the MDACS should be directed to:
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All latest versions of published documents and application forms for MDACS are available at MDCO website.

5 References

- [1] Global Harmonization Task Force: *Essential Principles of Safety and Performance of Medical Devices*. Final Document SG1-N41R9:2005.
- [2] Global Harmonization Task Force: *Information Document Concerning the Definition of the Term "Medical Device"*. Final Document SG1-N29R16:2005.

- [3] Global Harmonization Task Force: *Labelling for Medical Devices* Final Document SG1-N43:2005.
- [4] Global Harmonization Task Force: *Principles of Medical Devices Classification*. Final Document SG1-N15:2006.
- [5] Global Harmonization Task Force: *Principles of In Vitro Diagnostic (IVD) Medical Devices Classification*. Final Document SG1-N45:2008.