SENARAI PINDAAN

DOKUMEN PANDUAN

REQUIREMENTS FOR LABELLING OF MEDICAL DEVICES (MDA/GD/0026) – FIFTH EDITION

Bil	Perkara	Keperluan Pelabelan	Catatan
1.	4.1 General Requirement	b) A registered medical device shall be labelled with Malaysian medical device registration number and this shall be carried out within 6 months from the date of registration of the medical device. The use of QR code available from medical device registration certificate to indicate medical device registration number is encouraged. Examples of the format allowed: i. MDA Reg. No. xxxxxxx ii. Registered with MDA GXXXXX iii. Registration No. Gxxxxxxx iv. Gxxxxxxx v. Malaysia Reg. No. XXXXXXX vi. Medical Device Registration No. XXXXXXX vii. vii. MDA GXXXXX	Rujuk muka surat 4
		f) Paper versions of all labelling shall accompany all home use devices.	Rujuk muka surat 5
2.	4.5 Location of labelling	a) as far as it is practical and appropriate, the information needed to identify and use the medical device safely shall be provided on the medical device itself, and/or on the packaging for each unit (primary level of packaging), and/or the packaging of multiple medical devices (secondary level of packaging). If this is not practicable or appropriate, the information may be set out in the accompanying leaflet, manual, packaging insert, etc.	Rujuk muka surat 5
		b) the medical device registration number, and manufacturer/ authorised representative details and QR code (if available) shall be located where the information can be accessed at the point of sale by the customers/users.	
		e) for information that are provided on the label, Bahasa Malaysia translation shall be provided on the label itself.	
3.	4.8 General contents of labelling	4.8.1 The label of a medical device shall contain the following information: a) details of medical device to enable user to identify it, which include name (brand name, generic name and specified name) of the device, model and identifier;	Rujuk muka surat 6
		e) Name, address and contact details [email and/or phone number and/or website address] of the manufacturer and AR (in the case of foreign manufacturer) to obtain technical assistance.	
		k) any decommissioning or disposal information, if applicable and based on risk assessment (for example: infection or microbial hazards, environmental hazards; physical hazards)	Rujuk muka surat 7

		4.8.2 The information in 4.8.1 f) g) h) i) and other necessary information may be provided, in the form of insert or other types of labelling, after applying risk management as according to ISO 14971.	Rujuk muka surat 7
		4.8.3 For all labeling information, requirements on MDA/GD/0032, Code of Advertisement (COA) shall be observed.	
4.	4.9 Specific contents of labelling	a) For some medical devices, the following specific contents shall be included in the labelling: iii. treatment or handling, such as sterilisation, calibration, etc., that is needed before a medical device can be used. This includes information on the sterilisation method;	Rujuk muka surat 7
		vi. identification for a reusable medical device, information and instruction for cleaning, disinfecting, packaging and, where appropriate, the method of resterilisation, and identification on when the medical device or its accessory can no longer be reused (e.g., signs of material degradation or the maximum number of allowable reuses).	Rujuk muka surat 8
		viii. The medical device labelling for the purpose of: 1. demonstrations, please refer to the guidance document on Import and/or supply of unregistered medical devices for the purpose of demonstration for marketing or education (MDA/GD/0018); and 2. clinical research, please refer to the guidance document on Notification of Exemption from Registration of Medical Devices for The Purpose of Clinical Research or Performance Evaluation (MDA/GD/0016).	
5.	4.10 Instructions for use (IFU)	a) warnings, precautions or measures to be taken in the event of malfunction of the medical device or changes in its performance that may affect safety;	Rujuk muka surat 8
		b) warnings, precautions or measures to be taken in regards to the exposure to reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, or temperature;	Rujuk muka surat 9
		c) warnings, precautions or measures to be taken in regards to the risks of interference posed by the reasonably foreseeable presence of the medical device during specific diagnostic investigations, evaluations, therapeutic treatment or use (e.g., electromagnetic interference emitted by the medical device affecting other equipment);	
		d) precautions related to materials incorporated into the medical device that are endocrine disrupting, carcinogenic, mutagenic or toxic to reproduction or could result in sensitisation or allergic reaction of the patient or user;	
		e) warnings or precautions related to potentially infectious material present in the medical device;	

		f) warnings or precautions for a medical device administering medicinal or biological products, including information that indicates any limitations or incompatibility in the type of substances to be delivered;	
		h) warnings or precautions on hazardous or potentially hazardous radiation, including: i. the nature of the emitted radiation; ii. the means of protecting the users, bystanders, and patients; iii. including ways of avoiding misuse; and iv. iv. including ways of appropriately reducing the risks inherent during transport, storage and installation, where applicable.	
		i) for medical device with measuring function, the degree of accuracy claimed by the manufacturer;	
		k) a specification of the clinical benefit to be expected;	
		l) a summary of safety and clinical performance information relevant to the user or patient;	
		m) for medical device software, user instructions may be supplied in electronic data storage devices (e.g. compact disc, digital video disc, USB flash drive).	Rujuk muka surat 10
6.	4.12.1 Electronic IFU (e-IFU)	a) Electronic IFU (e-IFU) is eligible for devices that are limited to those intended for use by professional users only.	Rujuk muka surat 11
		b) Users shall always have the choice to obtain the content of the eIFU in paper form on request, without undue delay or within the time period specified in the risk assessment, and at no additional cost.	
		c) For information downloadable from the internet, the internet web address shall be clearly printed on the physical label of the device and displayed in such a manner that highlights to the user its purpose. The manufacturer /AR shall ensure that the information in electronic label is identical with the printed IFU approved in the product registration.	
		d) Manufacturers shall conduct and document a risk analysis for implementation of electronic IFUs and maintain records of this analysis. Specific points to address include: i. Does the intended user have the required level of experience and the means to use the electronic IFU (e.g. a computer with internet access at or near the device's point of use, CD/DVD Drive or a compatible web-browser)? ii. Are there back-up methods for accessing the electronic/hard-copy IFU? iii. Are there processes in place to ensure ongoing security of electronic IFU?	
		e) Manufacturers shall have defined procedures and processes for the establishment and revisions to electronic documents.	Rujuk muka surat 12

		f) Paper-form IFU is required and additional electronic IFU is optional for home use devices. Any changes to the electronic label shall comply with the specified requirements in Guidance on Change Notification for Registered Medical Devices (MDA/GD/0020).	
7.	4.12.2 E-IFU for Bahasa Malaysia translation for home use device	a) E-IFU is allowed for medical device intended for use by professional users only.	Rujuk muka surat 12
		b) Paper-form IFU is required and additional electronic IFU is optional for home use devices.	
8.	4.12.3 Instruction manual or operator manual or user manual in electronic format for professional use medical device	Product manual is recommended to be in printed form. However, electronic form is allowed to be provided subject to the following conditions: a) Manufacturers shall conduct and document a risk analysis for implementation of electronic manuals and maintain records of this analysis. Specific points to address include: i. Does the intended user have the required level of experience and the means to use the electronic (e.g. a computer with internet access at or near the device's point of use, CD/DVD Drive or a compatible web-browser)? ii. Are there back-up methods for accessing the electronic/hard-copy manuals? iii. Are there processes in place to ensure ongoing security of electronic manuals?	Rujuk muka surat 12
		b) Manufacturers shall have defined procedures and processes for the establishment and revisions to electronic documents.	
9.	4.13 Use of specific statements	Statements such as "Medical Device Authority (MDA)" and/or Ministry of Health Malaysia" (unless it required by Ministry of Health Malaysia) is prohibited in all labelling as it is considered as an endorsement from the Authority.	Rujuk muka surat 12
10.	4.14 Use of MDA Logo	Any logo of the Medical Device Authority (MDA) is prohibited to be placed in the medical device labelling.	Rujuk muka surat 12