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MEDICAL DEVICE GUIDANCE DOCUMENT

DECLARATION OF CONFORMITY (DOC)

Medical Device Authority
MINISTRY OF HEALTH MALAYSIA

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Preface

This Guidance Document was prepared by the Medical Device Authority (MDA) to help the industry and healthcare professionals in their quest to comply with the Medical Device Act (Act 737) and the regulations under it.

This Guidance Document shall be read in conjunction with the current laws and regulations used in Malaysia, which include but not limited to the following-

a) Medical Device Act 2012 (Act 737); and

b) Medical Device Regulations 2012.

In this Guidance Document, the following verbal forms are used:

- “shall” indicates a requirement;

- “should” indicates a recommendation;

- “may” indicates a permission; and

- “can” indicates a possibility or a capability.

Irrespective of the requirements of this Guidance Document, MDA has the right to request for information or material, or define conditions not specifically described in this document that is deemed necessary for the purpose of regulatory control.

MDA has put much effort to ensure the accuracy and completeness of this guidance document. In the event of any contradiction between the contents of this document and any written law, the latter should take precedence.

MDA reserves the right to amend any part of the guidance document from time to time.

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DECLARATION OF CONFORMITY

1. Introduction

Regulatory controls are intended to safeguard the health and safety of patients, users and the public.

Declaration of Conformity is one of the regulatory requirements imposed in the Medical Device Regulation 2012. It is an attestation drawn up by the manufacturer that its medical device fully conforms to all applicable Essential Principles of Safety and Performance (EPSP) of medical device and other requirements of Act 737 and the regulations under it.

2. Purpose

The purpose of this document is to explain further on the requirements of declaration of conformity to ensure compliance to the medical device regulatory requirements.

3. Scope

This document specifies the requirements on declaration of conformity for medical device registration. It applies to products that fall within the definition of a medical device, as defined in Section 2 of Medical Device Act 2012 (Act 737) which is further elaborated in the Guidance Document on Definition of Medical Device (MDA/GD/0006).

4. Terms and definitions

For the purposes of this document, the terms and definitions in Act 737, the regulations under it and the following terms and definitions apply.

4.1 Authority

The Medical Device Authority, Ministry of Health Malaysia.

4.2 Conformity assessment

The systematic examination of evidence generated and procedures undertaken by the manufacturer, under requirements established by the Authority, 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 for Medical Devices (EPSP).

4.3 Conformity assessment body (CAB)

As specified in Section 10 of the Medical Device Act 2012 (Act 737).

4.4 Manufacturer

As specified in Section 2 of the Medical Device Act 2012 (Act 737).

4.5 Recognised standards

Standards deemed to offer the presumption of conformity to specific essential principles of safety and performance.

4.6 Responsible person

Responsible person is the person appointed/authorised by the establishment who is responsible for related legal obligations and implications under Act 737 and its subsidiary legislations, including making submission for application for establishment licensing and medical device registration. Responsible person has the overall control and authority to make decision. Depending on the setup of an establishment, example of a responsible person may include the chief executive officer, managing director or general manager for a company.

4.7 Technical documentation

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 for Medical Devices (EPSP).

5. Requirements

DoC is prescribed in Appendix 3, Third Schedule of the MDR 2012. The manufacturer may use the DoC template in Annex A to draw up a declaration of conformity to comply with the DoC format as in Part II of Appendix 3 of MDR 2012. With the DoC, the manufacturer attests that its medical device complies fully with all essential principles for safety and performance and other requirements specified in the Act 737 and its regulations. The manufacturer shall also provide sufficient documents or evidence to support its DoC.

5.1 According to Item 9, Third Schedule of Medical Device Regulations 2012:

a) The manufacturer shall be required to attest that its medical device complies fully with all essential principles for safety and performance and shall draw up a declaration of conformity in the format as specified in Appendix 3 of the Schedule.

b) The conformity assessment body shall review and confirm the adequacy of the declaration of conformity by examining the supporting documents or

other evidence. DoC reviewed by CAB shall be uploaded in MeDC@St (web-based Online Application System).

c) Notwithstanding subparagraphs (1) and (2), the conformity assessment body may require additional document or information, as it thinks fit, to complete the review.

5.2 According to Item 1, Appendix 3, Third Schedule of Medical Device Regulations 2012:

a) For the purpose of registration of a medical device, a medical device manufacturer shall –

i. Attest that its medical device conforms to all applicable essential principles for safety and performance of medical device;

ii. Attest that its medical device complies fully with the requirements of the Act and its subsidiary legislations; and

iii. Draw up a written Declaration of Conformity.

b) Notwithstanding subparagraph (1), the manufacturer shall provide sufficient evidence to support its Declaration of Conformity.

6. The contents of DoC

Establishment may use the DoC template as provided in MeDC@St (web-based Online Application System). The DoC shall contain the following information:

a) Name and address of manufacturer.

b) An attestation that each device that is subjected to the declaration:

i. complies with all the applicable essential principles for safety and performance as described in Appendix 1 of Third Schedule MDR 2012 on Essential Principle of Safety and Performance of Medical Devices;

ii. has been classified according to the classification rules specified in First Schedule MDR 2012 on Rules of Classification Rules of Medical Device; and

iii. has met all the applicable conformity assessment elements.

c) Particulars of medical device as explained in Table 1 to identify the device to which the DoC applies.

d) The conformity assessment elements as specified in Third schedule of MDR 2012 have been applied;

e) Date from which the Declaration of Conformity is valid.

f) List of standards that is applicable to the medical device. List of standards should be as according to the individual medical device and this requirement is included in the QMS certification requirement.

g) Attestation on the responsibility and acknowledgement on the implication of Section 76 of the Act. Attestation shall be as prescribed in the DoC template in MeDC@St.

h) The name, position, and signature of the person responsible who has been authorised to complete the Declaration of Conformity on the manufacturer's behalf. Letter of authorization for person responsible shall be provided and signed by top management.

Table 1: Explanation on the particulars

Particulars	Explanation
Generic name	The name given to a medical device that is used to identify it irrespective of trademark or etc.
Specified name	The name of a medical device given by its manufacturer that identifies a manufacturer's medical device distinct from those of other manufacturers.
Brand/model	The name, term, design, symbol, or any other feature or identifier of a medical device given by its manufacturer that identifies a manufacturer's medical device distinct from those of other manufacturers.
Manufacturer	The name of manufacturer who owns the brand of the product.
Country of origin	The country of manufacturer.
Manufacturing site	Name and address of the manufacturing site
Risk-based classification	Class A/ B/ C/ D, as per Appendix 1 and Appendix 2, First Schedule, MDR 2012.
Classification rule	General medical device: Rule 1-16 of Appendix 1, IVD: Rule 1-7 of Appendix 2, First Schedule, MDR 2012.
GMDN code (preferably, if available)	The code to identify a medical device at generic level in a meaningful manner used by regional or national regulatory bodies. The code is an international nomenclature system provided by GMDN Agency.
Medical device registration number or any approval code	The registration number issued or pre-market approval code assigned by the Authority from GHTF founding members.

7. The signatory

The DoC shall be signed by the person as detailed out below:

i) For local manufacturer, the signatory is the top management or the person responsible as declared in 6 (h); and

ii) For foreign manufacturer, the signatory is any person in the top management category of the foreign manufacturer.

Top Management is the person responsible having the overall control and have the authority to make decision. Depending on the organization structure of the establishment. Person responsible includes Proprietor, President, Vice President, Director, Chief Executive Officer (CEO), Managing Director or General Manager.

Annex A
(Informative)

Declaration of Conformity Template

Name and Address of Manufacturer
(please print on Company Letterhead of Manufacturer)

DECLARATION OF CONFORMITY

I, *<please provide the name of person responsible for manufacturing the medical device>*, hereby declare that the below mentioned medical device-

(i) complies with all the requirements under the Act;

(ii) has been classified according to the classification rules as specified in First Schedule on Rules of Classification of Medical Device; and

(iii) conforms to requirements specified in APPENDIX 1 of Third Schedule on Essential Principles for Safety and Performance of Medical Devices under Medical Devices Regulations 2012.

(A) Particulars of medical device

Generic name:

Specified name:

Brand/model:

Manufacturer:

Country of origin:

Manufacturing site:

Risk-based classification:

Classification rule:
(Note: according to First Schedule on Rules of Classification of Medical Device)

GMDN code:

Medical device registration number or any approval code:

(B) Quality Management System certificate ("QMS")

Conformity Assessment Body issuing the certificate:

Certificate number:

Issuance date:

Expiry date:

Note:

i) For Class B, Class C and Class D medical devices, declaration of conformity to either of the following QMS standards is mandatory:

   (a) MS ISO 13485; or

   (b) Other quality management system standard recognised by the Medical Device Authority.

ii) For Class A medical devices that are not manufactured under either of the above mentioned quality management system standards, certification obtained for alternative quality management system standards shall be listed in this section, if applicable.

iii) For Class A medical devices with measuring function, conformity assessment certificate and calibration and metrology report, issue date, expiry date, calibration should be provided.

iv) For Class A medical devices with sterilization, validation report and conformity assessment certificate number, issue date, expiry date should be provided.

(C) Standard Applied

Please state and list all standards applicable for the above-mentioned medical device.

I am fully responsible with all the information provided in this declaration. This declaration of conformity is valid from ……. (Day) ……. (Month) ……. (Year).

I fully understand and acknowledge that it is an offence under Section 76 of the Medical device Act 2012 [*Act 737*] to make, sign or furnish any declaration, certificate or other document which is untrue, inaccurate or misleading.

Authorised Signatory:

_____ _____

Name/Position Date

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