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MEDICAL DEVICE GUIDANCE DOCUMENT

NOTIFICATION OF CUSTOM-MADE MEDICAL DEVICE

Medical Device Authority
MINISTRY OF HEALTH MALAYSIA

Contents

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);

b) Medical Device Regulations 2012;

c) Medical Device (Duties and Obligations of Establishments) Regulations 2019; and

d) Medical Device (Advertising) Regulations 2019.

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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NOTIFICATION OF CUSTOM-MADE MEDICAL DEVICE

1. Introduction

Placement and supply of a medical device in the Malaysian market requires the medical device comply with the requirement of the Medical Device Act 2012 (Act 737), including that the device be registered with the Medical Device Authority. The Medical Device (Exemption) Order 2016 however has provided the custom-made medical device to be exempted from the registration requirement under Section 5 of Act 737.

Custom-made medical devices are intended to cover special cases of users where commercially existing products or alternative therapies are inadequate to meet the needs and requirements of particular individuals.

It is the responsibility of the manufacturer to ensure custom-made medical device is comply with the relevant essential principles for safety and performance as specified in Appendix 1 of Medical Device Regulations 2012.

It is important to ensure that the custom-made medical device is not mass-produced and cannot be found or replaced by any other alternative in the market. The request to produce custom-made medical devices shall be written by a medical practitioners/healthcare professional in the form of a specific prescription and used with the requirements of the particular patient.

2. Scope and application

This guidance document is intended to provide guidance for the requirements of custom-made medical device that are eligible to be exempted under Medical Device (Exemption) Order 2016.

This guidance document specifies requirements and notification process for the applicant to obtain the permission from the Authority prior to the importation and/or placing of custom-made medical device in the market.

This document does not cover the medical device that are patient-matched, adaptable or mass-produced and these medical devices shall be registered with the Authority.

This guidance document is applicable to the establishments and medical practitioners/healthcare professional that are dealing with custom-made medical device.

3. Terms and definitions

3.1 adaptable medical device

A medical device that meets the following requirements:

a) It is mass-produced; and
b) It is adapted, adjusted, assembled or shaped at the point of care, in accordance with the manufacturer's validated instructions, to suit an individual patient's

specific anatomo-physiologic features prior to use.

[SOURCE: IMDRF Personalized Medical Devices- Regulatory Pathways 18 March 2020]

3.2 applicant

Applicant can be either establishment, healthcare practitioner, government department, government or private healthcare facility

3.3 custom-made medical device

A medical device made with a specific design characteristic in accordance with a medical practitioner's written prescription and is intended to be used for a particular patient.

[SOURCE: Medical Device Exemption Order 2016]

3.4 intended use/ purpose

The objective intent of the manufacturer regarding the use of a product, process or service as reflected in the specifications, instructions and information provided by the manufacturer.

3.5 label

Written, printed, or graphic information either appearing on the medical device itself, or on the packaging of each unit, or on the packaging of multiple devices.

NOTE. The definition above refers to the human readable label.

3.6 labelling

The label, instructions for use, and any other information that is related to identification, technical description, intended purpose and proper use of the medical device, but excluding shipping documents.

NOTES:

1. Labelling can also be referred to as "information supplied by the manufacturer."
2. Labelling can be in printed or electronic format and may either physically accompany the medical device or direct the user to where the labelling information can be assessed (such as through a website).

3.7 manufacturer

(a) a person who is responsible for-
  (i) the design, production, fabrication, assembly, processing, packaging and labelling of a medical device whether or not it is the person, or a subcontractor acting on the person's behalf, who carries out these operations; and
  (ii) assigning to the finished medical device under his own name, its intended purpose and ensuring the finished product meets the regulatory requirement;

or

(b) any other person who-
  (i) assembles, packages, processes, fully refurbishes, reprocesses or labels one or more ready-made medical devices; and
  (ii) assigning to the ready-made medical device under his own name, its intended purpose and ensuring the finished product meets the regulatory requirements,

but shall not include the following persons:
  (A) any person who assembles or adapts medical devices in the market that are intended for individual patients; and
  (B) any person who assembles, packages or adapts medical devices in relation to which the assembling, packaging or adaptation does not change the purpose intended for the medical devices.

[SOURCE: Medical Device Act 737]

3.8 mass produced medical device

A medical device that is based on standardised dimensions/designs, that is not designed for a particular individual; and that is typically produced in a continuous production run or homogenous batch.

[SOURCE: IMDRF Definitions for Personalized Medical Devices 18 March 2018]

3.9 patient-matched medical device

A medical device that meets the following requirements:

a) It is matched to a patient's anatomy within a specified design envelope using techniques such as scaling of the device based on anatomic references, or by using the full anatomic features from patient imaging; and
b) It is typically produced in a batch through a process that is capable of being validated and reproduced; and
c) It is designed and produced under the responsibility of a manufacturer even though the design may be developed in consultation with an authorized healthcare professional.

NOTES:

1. A written request from an authorized healthcare professional may be present; but is not mandatory.
2. The number and type of design inputs in consultation with a healthcare professional may vary depending on the medical devices to be manufactured.
3. The design must remain within the validated parameters of the specified design envelope.
4. Refer to Appendix E for examples of medical devices covers under patient-matched medical device.

[SOURCE: IMDRF Definitions for Personalized Medical Devices 18 March 2020]

3.10 medical practitioner

Any person who is registered as such under the Medical Act 1971 [Act 50] and who holds a valid practicing certificate.

3.11 healthcare professional

Medical practitioner, dental practitioner, pharmacist, clinical psychologist, nurse, midwife, medical assistant, physiotherapist, occupational therapist and other allied healthcare professional as listed in the 2nd Schedule of Allied Health Professions Act 2016 (Act 774).

[SOURCE: Private Healthcare Facilities and Services Act 1998 (Act 586)].

3.12 specific design characteristics

Unique design specifications, necessary to produce custom-made devices, that are based on an individuals' specific anatomo-physiological features and/or pathological condition; and that cannot be proposed by a manufacturer without the involvement of a healthcare professional.

[SOURCE: IMDRF Definitions for Personalized Medical Devices 18 March 2018]

4. Requirements

4.1 General requirements

a) A custom-made medical device shall meet the following requirements:

i. It is intended for the sole use of a particular patient; and

ii. is manufactured by the manufacturer in accordance with a written prescription of a medical practitioner/healthcare professional and with particular design characteristics specified by that medical practitioner/healthcare professional in the request (even if the design is developed in consultation with the manufacturer), where those design characteristics are intended to address:
(i) either or both of the anatomical and physiological features of the intended particular patient; or
(ii) a pathological condition of the intended particular patient; and

b) Medical devices that are patient-matched, adaptable or mass produced shall not be considered as custom-made medical device. Refer to Annex C for further explanation on the characteristics and their examples.

4.2 Requirements for the manufacturers

a) According to the Medical Device (Exemption) Order 2016, the custom-made medical devices have been exempted from medical device registration. However, the manufacturer shall ensure the custom-made medical devices place in the market meet the safety and performances requirements and shall fulfill the exemption requirements as follows:

i. meets all the criteria of the custom-made medical device, including obtaining the written prescription and specific design characteristics from medical practitioner/ healthcare professional;

ii. conformity assessment procedures have been applied relevant to its classification, demonstrating it, and all device it produces meet all relevant

Essential Principles of Safety and Principles (EPSP) of medical device;

iii. determine the classification of the device according to the device classification as specified in First Schedule of Medical Device Regulation 2012 and further elaborated in the Guidance Document on The Rules of Classification for General Medical Devices (MDA/GD/009);

iv. technical documentation of custom-made medical device complies with the standard regulatory requirements in accordance with Appendix 2 of Schedule 3 of MDR 2012 and shall be available upon request.

4.3 Requirements for written prescription

a) A written prescription shall be issued by a medical practitioner/healthcare professional.

b) At minimum, it shall contain:

i. the name of the particular patient (or pseudonym if relevant).

ii. specific design characteristics made by the medical practitioner/healthcare professional which are unique to the particular patient's anatomic-physiological features and/or pathological condition.

iii. planned surgery date or medical device application date (where applicable).

c) The following (non-exhaustive) additions can accompany a written prescription and if so, also constitute specific design characteristics:

i. models (physical or 3D model data).

ii. moulds (e.g. for dental or orthotic purposes).

iii. dental impressions

4.4 custom-made medical device statement

a) The manufacturer shall submit a statement of the custom-made medical device.

b) Annex B provides the template of custom-made medical device statement.

c) The statement shall include:

i. data allowing identification of the device, i.e., description, serial number, order number, generic name;

ii. a section that indicates that the device is intended for a particular patient, together with the name of the individual (this may be an identification number if confidentiality needs to be maintained, provided it can be traced through records to the named individual);

iii. the name of the medical practitioner/healthcare professional who requested the device, and, where applicable, their healthcare facility;

iv. particular design characteristics specified by that medical practitioner/healthcare professional in the request (even if the design is developed in consultation with the manufacturer); and

v. the name and address of the manufacturer.

4.5 Labelling

The following specific contents that shall be included in the labelling of the custom-made medical device are as prescribed in 4.2 i) and ii).

4.6 Advertising

In accordance with the provisions under Section 44 (1) that states "No person shall advertise a medical device unless the medical device has been registered and complied with the requirements of this Act", therefore advertisement of custom-made medical device is not allowed as according to Section 44 of Act 737.

5. Notification process

5.1 Notification form

The applicant shall submit the notification form together with required information/documents as described in Annex A and Annex B to the Medical Device Authority (MDA) by email at **sa.cm@mda.gov.my.**

5.2 Administrative charge

a) Upon receipt of application, the Authority will issue a payment advice to the applicant. All fees shall be paid 30 days after notifications on the payment advice. Applications will be dropped if the payment is not received within the specified time.

b) Each notification shall be submitted together with a RM 300 administrative charge, with the following conditions:

i. Administrative charge shall be paid through bank draft or online transfer. Cash will not be accepted. The Authority will not be responsible for the cash sent or brought to MDA.

ii. Payable to "KUMPULAN WANG PIHAK BERKUASA PERANTI PERUBATAN". Name, telephone number of the applicant and a statement of "Notification for Custom-made Medical Device" must be written at the back of the bank draft but not in the table section.

iii. The administrative charge is non-refundable.

5.3 Notification review

a) Upon receipt of notification and relevant documents, the Authority will review the notification and if, after consideration of all the information provided, the Authority considers that all requirements have been fulfilled, the Authority will notify the applicant, of its decision and issue a "No restriction letter" permitting the applicant to import and/or place the medical device in Malaysian market.

b) If the Authority considers that the information provided is incomplete, the Authority may request the missing/incomplete information from the applicant. Any additional information, particulars or documents required by the Authority shall be provided by the applicant within 30 working days from the date of request by the Authority.

c) The turn-around time per application is 21 days upon submission of complete form and supporting documents.

d) The Authority has the right to revoke the "No restriction letter" letter if in its opinion, there has been a breach or non-compliance with the specified terms and conditions and/or duties and responsibilities of the applicant.

6. Conditions on notification

The applicant shall be fully responsible for handling the custom-made medical device including:

a) notify the Authority on the importation and/or placing of custom-made medical device in the market.

b) the exemption is only applicable to medical device and site as listed in Annex A which is based on the information given by the applicant;

c) fully responsible for the importation and placement of this exempted medical device, including supply chain activities.

d) submit any information requested by the Authority within the prescribed period;

e) used only in accordance with the purpose as declared in the Notification submission;

f) advertisement of custom-made medical device is not allowed as according to Section 44 of Act 737;

g) comply with any directions issued by the Authority from time to time and allow for inspection from Authority at any time without prior notice;

h) keep all information pertaining to this medical device and shall be made available upon request by the Authority at any time;

i) responsible to comply with requirements of post market surveillance and vigilance as according to Chapter 3 of Act 737 and Medical Device (Duties and Obligations of Establishments) Regulations 2019;

j) The Authority reserved the right to make a visit or inspection to the person or establishment at any time without prior notice;

k) maintain traceability of custom-made medical device throughout the supply-chain being dealt with, which include the quantity supplied, the batch or lot number and/or model and serial number;

l) maintain records relating to the custom-made medical device, including notification form as in Annex A and a copy of statements as in Annex B and evidence that the device conforms to the Essential Principles for a period of 5 years on top of the projected useful life of the medical device as determined by the manufacturer (for example, if the projected useful life of the medical device is one year, the records

should be kept for six years).

m) The Authority may revoke the Custom-Made Medical Device Exemption if the person or establishment fails to comply with any conditions imposed by the Authority.

Annex A
(informative)

Notification for Custom Made Medical Device

NOTIFICATION FOR CUSTOM MADE MEDICAL DEVICES (In accordance with Medical Device (Exemption) Order 2016)
All field are mandatory unless stated otherwise
SECTION A: APPLICANT DETAILS Applicant can be either an establishment, medical practitioner/ healthcare professional, government department, government or private healthcare facility
1. *Please tick the appropriate box:*
☐ Establishment Types of establishment: ☐ Local Manufacturer ☐ Authorized Representative ☐ Distributor ☐ Importer ☐ Others. Please specify:
2. Name of Applicant:
3. NRIC No./Passport: | 4. Designation:
5. Name & Address of Organization:
6. Telephone No.: | 7. Email Address:

8. Does the company already hold Establishment License or has submitted establishment license application *(if applicable)?*	☐ Yes If Yes, please state the company Establishment License Number or From Identification (Form ID): ……	☐ No

SECTION B: PRESCRIBER DETAILS *Note: Medical Practitioner; or Healthcare Professional User (e.g.: Dentist, Optometrist, Orbital Prosthetist, Ocularist, Audiologist, Orthotist, Orthopaedic Shoe Fitter, or Hearing Aid Dispenser)*	
1. Name:	
2. Title:	3. Annual Practicing Certificate Number:
4. Telephone No.:	5. Email Address:
6. Health Care Facility Name & Address:	
SECTION C: CUSTOM MADE MEDICAL DEVICE MANUFACTURER DETAILS *Note: Manufacturer is the legal person with responsibility for the design, manufacture, packaging and labelling of the device under his own name before it is placed on the market)*	
1. Name & Address of Organization:	
2. Contact person:	
3. Contact details: Email: Phone/Fax Number:	
SECTION D: CUSTOM MADE MEDICAL DEVICE DETAILS *Note: Mass-produced devices, which need to be adapted to meet the specific requirements of a healthcare professional (and which are supplied for the sole use of a particular patient), are **not** considered to be custom-made devices*	
Please provide details of the medical device in **Appendix A**	
Please provide following supporting document: - A copy of statements for custom-made medical device that contain information about the description, serial number, name of the patient, name of the authorized person who made the prescription, the name and address of the manufacturer, etc. as specified in Annex B; and - Written prescriptions as specified in 4.3 Requirements for written prescription in Guidance Document MDA/GD/XXXX Notifications for Custom-made Medical Device.	
SECTION E: PATIENT DETAILS	
Patient's ref No (MRN /HIS):	

SECTION F: ATTESTATIONS & DECLARATION

I, the undersigned hereby declare that

i. This/These product(s) is/are a medical device in accordance to the definition of medical device set out in Section 2, Medical Device Act 2012 (Act 737).

ii. This/These product(s) has/have met the definition of a custom-made medical device that are:

- Has been manufactured specifically in accordance with a written specification by a health professional specifying its design characteristic or construction.
- Intended to be used only in relation to a particular individual, or by a health professional to meet special needs arising in the course of his or her practice

iii. The medical device(s) conform(s) to all relevant essential principles for safety and performance, set out in the Appendix 1 of Third Schedule of the MDR 2012.

iv. The medical device(s) has/have met all the labelling requirements set out in the Sixth Schedule of the MDR 2012.

v. The technical documentation of the custom-made device(s) is/are prepared in accordance with the *format* as specified in Appendix 2 of Schedule 3 of MDR 2012 and is/are available upon request by the Authority.

vi. Manufacturing Process

Remark: Any kind of deletion in Section F please provide justification

I shall be responsible for the establishment and implementation of post-market surveillance and vigilance system to monitor safety and performance of this/these medical device(s).

I, the undersigned, **hereby attest that** the information and attachment provided on this notification is/are accurate, correct, complete and current to this date. I understand that any declaration by me in this application that is untrue, inaccurate or misleading shall be liable to a fine not exceeding **RM 500,000.00** or to imprisonment for a term not exceeding **3 years** or to both. (Section 76 Act 737 refers).

Signature:

Person Responsible Name:

Designation:

Date:

Company stamp:

Appendix A:

Name of Medical Device:	
Medical Device Grouping:	☐ Single ☐ System ☐ Family ☐ Set
Medical Device Description:	
Brand/ Model:	
Model:	
Intended use of the medical device:	
Manufacturer's Name *(as it appears on the label)**:***	
Class:	
Classification Rule: (according to First Schedule on Rules of Classification of Medical Device, MDR 2012)	
Marketing Approval Status in other country(-ies) (Please state the	☐ Registered /Licensed …… …… ☐ Exempted/ Notified …… …… ☐ Others (please specify) …… … ……

name (s) of country (-ies) and provide supporting documents as evidence)	…… …… … …… …… …… …… …… …
Medical Device usage category (please tick the appropriate box)	☐ Dental Appliances ☐ Artificial Eyes/Cosmetic Shells ☐ Maxillofacial Prosthesis ☐ Hearing Aid Inserts/Moulds ☐ In-the-Ear Aids ☐ Orthopaedic Footwear ☐ Joint Replacement Implants ☐ Prosthetics and Orthotics ☐ Others (please specify):
Grouping List:	**Not Applicable to single medical device**

No.	Name of medical device, accessories, components, or articles as per product label:	Model	Medical Device Description

Annex B
(informative)

Template for Statement of Custom-Made Medical Device

This custom-made medical device was manufactured **by [insert name and address of manufacturer]**. The device is a **[insert a brief description of the device]** that can be identified by the following features-

- ***Briefly outline any identifying features of the device e.g. any branding it may carry, the colour of the material, the size of the device etc.***

The device is packaged **alone/along with the following-**

- ***List all other contents of the packaging***

The device was custom-made for- and intended only to be used in relation to- **[insert the name of the particular patient to whom the device is intended to be used],** according to specifications provided by **[insert the name and business address of the medical practitioner/healthcare professional who provided the specifications for the device].**

The following **design and/or construction** characteristics of the device we specified by **[insert the name of medical practitioner/healthcare professional who provided the specifications for the device]** when they requested the device be manufactured:

Characteristics	Specifications
e.g. length	*15 mm*

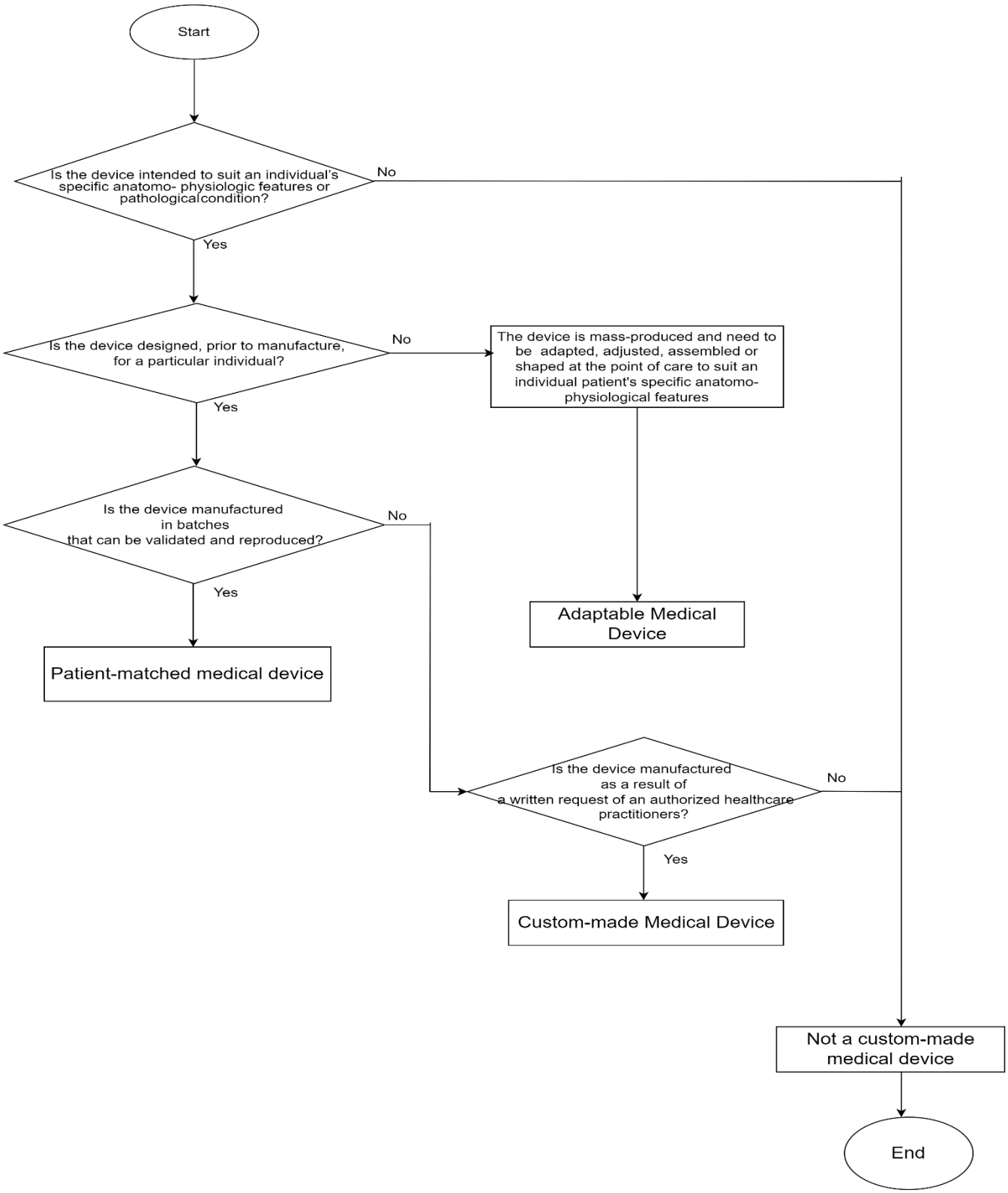
[Insert the name of the manufacturer] certifies that the device complies/does not comply with all the relevant essential principles for safety and performance as stated in Appendix 1 of Third Schedule of the MDR 2012.

This statement was compiled by the person name below:

[Signature]
[Full Name]
[Designation of Senior Company Official]
[Company stamp]
[Date]

Annex C
(informative)

Decision Tree to classify custom-made medical device.



Annex D
(informative)

Examples of custom-made medical device that are prescribed by the medical practitioner/healthcare professional

Table 1 shows the examples of custom-made medical device with different categories

Device Type	Medical practitioner/healthcare professional	Manufacturer
Dental appliances	Dentist	Dental laboratories
Artificial eyes/Cosmetic shells	Ocularist/orbital prosthetist	Ocularist or ocular technician
Maxillofacial prothesis	Prosthetist	Prosthetist
Hearing aid inserts/moulds	Audiology technician or audiologist	Insert maker
In-the-Ear Aids	Audiology technician or audiologist	Aid manufacturer
Orthopaedic footwear	Orthotist	Orthopaedic footwear manufacturer
Joint replacement implants (designed for a particular patient)	Orthopaedic surgeon	Implant manufacturer
Prosthetics and Orthotics	Rehabilitation consultant, orthopaedic consultant, prosthetists or orthotists	Prosthetic and Orthotic service companies and manufacturers

Annex E
(informative)

Examples of Custom-Made, Adaptable or Patient-Matched Medical Device

Example 1

ABC Company manufactures a mass-produced knee ankle foot Orthosis (KAFO) used to control instabilities in the knee and lower limb by maintaining proper alignment and controlling motion.

In this example, KAFO is an **adaptable medical device** because it meets the following requirement:

- Mass-produced; and
- Intended by the manufacturer to be assembled or adapted after it has been supplied in order to address an anatomic feature of the particular patient.

Example 2

XYZ Company is a manufacturer for orthopedic implants with ability to mass-produced existing and personalization of medical device. A medical practitioner contacted the company to request a personalized acetabular cage and cup for a particular patient, Dora, an 81-year-old female patient who needs to undergo a revision complicated procedure by complete loss of the anterior column and marked bone loss through the remaining acetabulum.

The medical practitioner sends the patient's information such as age, height and weight and consult with the manufacturer for the design of the device on certain features such as how the device should attach to the bone.

The manufacturer is able to produce the device within the scope of the specified design envelope and use the same production and verification methods with their existing medical devices.

In this example, the personalized medical device is a **patient-matched medical device** because it meets the following requirements:

- has been designed by the manufacturer within a specified design characteristics to fit the particular anatomy and physiology of a particular patient; and
- has been produced using a process capable of being validated and/or verified and reproduced.

Example 3

An orthopaedic surgeon wants to request a personalized medical device of femoral prosthesis from the orthopedic manufacturer. The patient has a damaged hip joint and severe pain due to a traumatic fall. Based on the surgeon's written request to the manufacturer, she designed the characteristics of an expandable distal femoral prosthesis for the patient, to replace the tumour distal femur bone.

The manufacturer designs and produces the expandable distal femoral prosthesis for the particular patient; based on the information supplied by the orthopaedic surgeon.

Thus, the expandable distal femoral prosthesis is a **custom-made medical device** because it meets the following requirements:

- is intended for the sole use of a particular patient; and
- is prescribed based on the written request from the medical practitioner; and
- is designed with particular design characteristics specified by the medical practitioner/healthcare professional to address the anatomical features of the particular patient; and
- the design of the medical device is outside the specific design characteristics of the manufacturer; and
- is not mass produced.

Example 4

An orthopedist requested a 3D implant prothesis to replace the diseased joint parts and restore joint function to a 3D printing implant manufacturer. The manufacturer used 3D printer based on the orthopedist's prescription from the patient's CT scan images. These includes the dimensions of the cemented medullary needle, 3D printing distal tibial prosthesis and the number, type and positions of fixation screws.

Thus, the 3D implant prosthesis is a **custom-made medical device** because it meets the following requirements:

- is intended for the sole use of a particular patient; and
- is prescribed based on the written request from the medical practitioner; and
- is designed with particular design characteristics specified by the medical practitioner/healthcare professional to address the anatomical features of the particular patient; and
- the design of the medical device is outside the specific design characteristics of the manufacturer; and
- is not mass produced.

MEDICAL DEVICE AUTHORITY

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