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# **MEDICAL DEVICE GUIDANCE DOCUMENT**

## **REQUIREMENTS FOR APPLICATION OF CERTIFICATE OF FREE SALE (CFS), MANUFACTURING CERTIFICATE (MC) AND CERTIFICATE OF FREE SALE FOR EXPORT ONLY (CFS EO) MEDICAL DEVICES**



**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);
- 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 incident 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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## **REQUIREMENTS FOR APPLICATION OF CERTIFICATE OF FREE SALE (CFS), MANUFACTURING CERTIFICATE (MC) AND CERTIFICATE OF FREE SALE FOR EXPORT ONLY (CFS EO) MEDICAL DEVICES**

### **1. Introduction**

Section 5(1) of Act 737 requires all medical devices are registered before they can be imported, exported or placed in the market. However, export only medical devices are exempted from registration as per Circular Letter of Medical Device Authority No. 4 Year 2018, *Exemption from Registration Requirement for Export Only Medical Device*.

This guidance document is developed to assist applicants in their application for Certificate of Free Sale (CFS), Manufacturing Certificate (MC) and Certificate of Free Sale for Export Only (CFS EO) medical devices.

### **2. Scope and application**

This guidance document applies to all products that fall within the definition of medical device, as defined in Section 2 of Act 737 and MDA/GD/0006, *Definition of Medical Device*, including in vitro diagnostic (IVD) medical devices.

This guidance document applies to any person who wish to apply for CFS or MC for the purpose of export registered medical device and shall comply with regulatory requirement in importing countries.

This document also applies to any person who wish to apply for CFS EO for medical devices that fall under the Circular Letter of Medical Device Authority No. 4 Year 2018, *Exemption from Registration Requirement for Export Only Medical Device*.

### **3. Terms and definitions**

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

#### **3.1 Authority**

Medical Device Authority established under Section 3 of Medical Device Authority Act 2012 (Act 738).

#### **3.2 contract manufacturer**

Any physical manufacturer that manufactures a medical device under contract for the "Manufacturer" as defined in 3.3.

#### **3.3 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 requirement,

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.

### **3.4 medical device**

As defined in Section 2, Act 737 and guidance document MDA/GD/0006, *Definition of Medical Device*.

### **3.5 physical manufacturer**

Any person who performs the activity of manufacture.

[SOURCE: ASEAN Medical Device Directive (AMDD)]

### **3.6 Certificate of Free Sale (CFS)**

Certificate issued as proof of registered medical devices, are legally exported or distributed in Malaysian market, freely without restrictions, and approved by the Authority in the country origin.

### **3.7 Manufacturing certificate (MC)**

Certificate issued to confirm that the medical device has been made by the specific manufacturer in Malaysia.

### **3.8 Certificate of Free Sale for export only (CFS EO)**

Certificate issued as proof of exempted medical devices under section 5 of Act 737, not been sold or distributed in Malaysian market, have obtained Notification of Export Only from the Authority to export their medical device to requesting country.

## 4. Requirements

### 4.1 Confirm product as a medical device

**4.1.1** The applicant is responsible to confirm that their products are medical devices. Such products which do not meet the medical device definition are not eligible for this requirement.

**4.1.2** The applicant who require confirmation if their product is a medical device may refer to guidance document MDA/GD/0006 *Definition of Medical Device* or submit the 'Product Classification application form' to [classification@mda.gov.my](mailto:classification@mda.gov.my) to determine the classification of the products. The guidance document and form are available to be downloaded at MDA website <https://portal.mda.gov.my/>

### 4.2 Risk based classification and grouping of medical device

The primary responsibility for determining a medical device risk classification and grouping is placed on the manufacturer. The manufacturer is responsible to determine medical device classification and grouping based on Medical Device Regulations 2012.

### 4.3 Quality Management System (QMS)

Manufacturers and contract manufacturers shall be certified to MS ISO/ ISO 13485; *Medical devices - Quality management systems - Requirements for regulatory purposes* by an accredited certification body.

### 4.4 Application procedure

**4.4.1** The applicant who requires CFS, MC or CFS EO shall submit the complete application 'Application on certificate of free sale (CFS) / manufacturing certificate (MC) or certificate of free sale for export only (CFS EO)' together with relevant documents via online form on MDA portal.

**4.4.2** The information and documentation required for application of CFS, MC or CFS EO are as per listed in Table 1, Table 2 and Table 3, respectively.

**Table 1 Requirements for Certificate of Free Sale (CFS)**

No	Requirements	Explanation
a)	A copy of establishment license	Please provide valid copy of establishment License
b)	Proof of medical device registration (Registration certificate)	Please provide valid copy of Registration certificate

No	Requirements	Explanation
c)	<p>Medical device list (Product details)</p> <ol style="list-style-type: none"> <li>Validity required (2 years or 5 years)</li> <li>Medical device name or brand and the registration number.</li> </ol> <p>NOTE Refer to Annex G for Medical device(s) list</p>	<p>Please upload complete medical device list in Word format:</p> <ol style="list-style-type: none"> <li>Please choose of validity required (write Yes in the requested validity, choose only one)</li> <li>Please list the medical device name or brand and the registration number.</li> </ol> <p>NOTE 1 Registered Brand – please provide registration number</p> <p>NOTE 2 OEM brand – declaration letter similar with registered brand shall be provided</p>

**Table 2: Requirements for Manufacturing Certificate (MC)**

No	Requirements	Explanation
a)	Registrar of Companies (ROC) certificate of applicant	<p>Please provide copy of Registrar of Companies (ROC) certificate of applicant</p> <p>NOTE Not applicable for licensed manufacturer</p>
b)	A copy of establishment license	<p>Please provide valid copy of establishment License.</p> <p>NOTE Not applicable for OEM Manufacturer</p>
c)	<p>Copy of Quality Management System Certificate (QMS)</p> <ol style="list-style-type: none"> <li>ISO 13485; or</li> <li>Equivalent QMS recognized by the Authority</li> </ol>	<p>Please provide valid copy of Quality Management System Certificate. Only QMS certificate that is still valid during evaluation process will be accepted.</p> <p>NOTE Not applicable for licensed Manufacturer</p>
d)	Proof of medical device registration (Registration certificate)	<p>Please provide valid copy of Registration certificate.</p> <p>NOTE Not applicable for OEM Manufacturer</p>
e)	Copy of Invoice (Evidence that this medical device is sold in Malaysia)	Please provide copy of Invoice

No	Requirements	Explanation
f)	<p>Medical device list (Product details)</p> <ol style="list-style-type: none"> <li>1. Validity required (2 years or 5 years)</li> <li>2. Medical device name or brand and the registration number.</li> </ol> <p>NOTE Refer to Annex G for Medical device(s) list.</p>	<p>Please upload complete medical device list in word format:</p> <ol style="list-style-type: none"> <li>1. Please choose of validity required (write Yes in the requested validity, choose only one)</li> <li>2. Please list the medical device name or brand and the registration number.</li> </ol>
g)	<p>Letter of declaration as OEM</p>	<p>Please provide letter of declaration of OEM.</p> <p>NOTE Not applicable for export only manufacturer.</p>
h)	<p>Brochure</p>	<p>Please provide product brochure.</p> <p>NOTE Not applicable for export only manufacturer.</p>

**Table 3: Requirements for CFS application for export only**

No	Requirements	Explanation
a)	<p>Acknowledgement on Notification for export only medical device.</p>	<p>Please provide acknowledgement on Notification by applying the "Notification for export only medical device".</p>
b)	<p><b>General information</b></p>	
	<p>i. Is the medical device for export only?</p>	<p>Please tick the appropriate box.</p>
	<p>ii. Does the medical device contain any active ingredient, poison or drug?</p>	<p>Please tick the appropriate box. If yes, kindly attach information on the active ingredient, poison or drug.</p>
	<p>iii. Type of medical device.</p>	<p>Please tick the appropriate box.</p>
	<p>iv. Class of medical device.</p>	<p>Please select the risk class of medical device based on the classification rules of medical device based on Second Schedule of Medical Device Regulations 2012 and MDA/GD/0009, The Rules of Classification for General Medical Devices, or MDA/GD/0001, IVD Medical Device Classification System.</p>



No	Requirements	Explanation
	v. Classification rules.	<p>Please select the classification rule that applies to the medical device based on the classification rules of medical device as specified in Second Schedule of Medical Device Regulations 2012 to justify the risk class chosen above.</p> <p>For Class A medical device, please select whether the device is non-sterile/ sterile/ with measuring function/ non-measuring function/ active/ non-active. Kindly attach relevant validation report for sterile medical device (sterilization validation report); calibration and metrology report for medical device with measuring functions; and electrical safety test report for active medical device.</p>
	vi. Medical device category.	Please select the medical device category that is applicable to the device. Please refer to the medical device category as per listed in Annex H.
	vii. Medical device name.	<p>Please provide the general name of the medical device as per described in the brochure/ catalogue/ label/ product specification document.</p> <p>EXAMPLE powder free latex examination glove, natural rubber latex male condom, automatic operated disposable lancet, peripheral vascular catheter.</p>
	viii. Description of medical device.	A description of the medical device if the medical device contains animal or human cells, tissues and/or derivatives thereof, rendered non-viable (e.g. porcine heart valves, catgut sutures, etc.); cells, tissues and/or derivatives of microbial or recombinant origin (e.g. dermal fillers based on hyaluronic acid derived from the bacterial fermentation processes); and/or irradiating components, ionizing (e.g. x-ray) or non-ionising (e.g. lasers, ultrasound, etc.), a description shall be provided.
	ix. Information on the product formulation* (applicable for medical device that contains	Please provide the information on any active ingredient/ poison/ drug

No	Requirements	Explanation
	any active ingredient/ poison/ drug).	contained in the medical device. You may list all in the template provided.
	x. Intended use of the medical device.	Intended use of the medical device is intended, for which it is suited according to the data supplied by the manufacturer in the instructions as well as the functional capability of the device.
	xi. Indications.	A general description of the disease or condition that the device will diagnose, treat, prevent, cure or mitigate and includes a description of the target patient population for which the device is intended.
c)	<b>Quality Management System (QMS) Certificate</b> – MS ISO/ ISO 13485.	Please provide MS ISO/ ISO 13485 certificate. Only QMS certificate that is still valid during evaluation process will be accepted.
d)	<b>Grouping.</b>	Various brands may be listed under same grouping (for same medical device).  The grouping of medical device shall be done according to the rules of medical device grouping as specified in Second Schedule of Medical Device Regulation 2012 and further elaborated in the Guidance Document on Product Grouping, MDA/GD/0005.
e)	<b>Summary of technical documentation (Common Submission Dossier Template, CSDT).</b> (Not applicable for Class A).	
	i. Executive summary.	Refer clause 4.4.2.
	ii. Essential Principles of Safety and Performance of Medical Devices (EPSP)/ Essential Requirements Checklist (ERC)/ ASEAN Medical Device Directive (AMDD)'s EPSP.	Evidence of safety and performance/ applied product standards/ sterilization standard (where relevant) shall be provided.
	iii. Description of medical device.	Refer clause 4.4.3.
	iv. Summary of Design Verification and Validation Documents:	

No	Requirements	Explanation
	<ul style="list-style-type: none"> <li>- Summary of clinical evidence (consist of objective, method, result, discussion, conclusion).</li> </ul>	Not applicable.
	<ul style="list-style-type: none"> <li>- Summary of Pre-Clinical Test (consist of objective, method, result, discussion, conclusion).</li> </ul>	Not applicable.
	<ul style="list-style-type: none"> <li>- Use of existing bibliography.</li> </ul>	Not applicable.
	<ul style="list-style-type: none"> <li>- Relevant safety and validation report.</li> </ul>	Kindly attach relevant validation report for sterile medical device; calibration and metrology report for medical device with measuring functions; and electrical safety test report for active medical device.
	v. Medical Device Labelling <ul style="list-style-type: none"> <li>- Sample of label shall be provided for medical device.</li> </ul>	Sample of label for each medical device brand shall be submitted. Provide a declaration that the medical devices are the same for the brands listed in Excel file (refer Annex B).
	vi. Risk Analysis.	Not applicable.
	vii. Manufacturer information (manufacturing process).	Refer to Clause 4.4.4.
f)	<b>Premarket approval</b> (Certificate/ report/ self-declare).	Premarket approval including from importing countries (if available) shall be submitted.
g)	<b>Post-market vigilance history</b> (within the last 5 years). <ul style="list-style-type: none"> <li>- Manufacturer information; and</li> <li>- Corrective Action Report (CAR); or</li> <li>- Corrective Action and Preventative Action (CAPA) (medical device under registration); or</li> <li>- Any ongoing Post-Market Issues.</li> </ul>	Manufacturer/ Contract manufacturer shall provide information on Post-market vigilance history of the medical device.  A declaration letter shall be submitted if there are no on-going post market issues.
h)	<b>Declaration of Conformity (DoC)</b> for Manufacturer/ contract manufacturer.	It is the responsibility of the manufacturer /contract manufacturer for preparing and signing the DoC as

No	Requirements	Explanation
		per Annex B. For further explanation, please refer to Clause 4.4.5.
i)	Attestation.	Applicant shall make an attestation for CFS application as per Annex A.

#### 4.4.2 Executive summary:

An executive summary shall be provided with the CSDT, which shall include the following information:

- a) an overview which covers an introductory descriptive information on the medical device, the intended uses and indications for use of the medical device, any novel features (e.g. nanotechnology);
- b) commercial marketing history which covers the list of countries where the medical device is marketed and the dates of introduction into those countries;
- c) intended uses and indications in its label;
- d) list of regulatory approval or marketing clearance obtained including the registration status, intended use and indications of the medical device in all reference agencies; copies of certificates or approval letters from each reference agency and declaration on labelling, packaging and instructions for use (IFU);
- e) status of any pending request for market clearance; and
- f) important safety and performance related information which include-
  - i. summary of reportable adverse events and field corrective actions (FCAs); and
  - ii. a description of the medical device if the medical device contains animal or human cells, tissues and/or derivatives thereof, rendered non-viable (e.g. porcine heart valves, catgut sutures, etc.); cells, tissues and/or derivatives of microbial or recombinant origin (e.g. dermal fillers based on hyaluronic acid derived from the bacterial fermentation processes); and/or irradiating components, ionizing (e.g. x-ray) or non-ionising (e.g. lasers, ultrasound, etc.), a description shall be provided.

#### 4.4.3 Description of medical device:

- a) A complete description of the medical device.
- b) Principles of operation or mode of action.
- c) Risk class and applicable classification rule for the medical device according to the Rules of Classification for General Medical Devices as specified in Appendix 1 of First Schedule of Medical Device Regulations 2012.
- d) A description of the accessories, other medical devices and other products that are not medical devices, which are intended to be used in combination with the medical device. For example, patients implanted with a stent or heart valve need

to be managed with appropriate medication such as warfarin, as recommended by the manufacturer.

- e) A description or complete list of the various configurations of the medical device for CFS/MC application. This is to be provided using the format as in Annex I.
- f) A complete description of the key functional elements (e.g. its parts or components, including software if appropriate), its formulation (e.g. if it is combined with drug component, the formulation needs to be described as well), its composition and its functionality.
- g) An explanation of any novel features.

Where appropriate, this will include labelled pictorial representation (e.g. diagrams, photographs and drawings), clearly indicating key parts/components, including sufficient explanation to understand the drawings and diagrams.

- h) Intended use of the medical device is intended, for which it is suited according to the data supplied by the manufacturer in the instructions as well as the functional capability of the device.
- i) Indications which is a general description of the disease or condition that the device will diagnose, treat, prevent, cure or mitigate and includes a description of the target patient population for which the device is intended.
- j) Instructions of use including the procedures, methods, frequency, duration, quantity and preparation to be followed for safe use of the medical device. Instructions needed to use the device in a safe manner shall, to the extent possible, be included on the device itself and/or on its packaging by other formats/forms.
- k) Contraindications.
- l) Warnings to inform on specific hazard alert that a user needs to know before using the device.
- m) Precautions to exercise special care necessary for the safe and effective use of the device. They may include actions to be taken to avoid effects on patients/users that may not be potentially life-threatening or result in serious injury, but about which the user should be aware. Precautions may also alert the user to adverse effects on the device of use or misuse and the care necessary to avoid such effects.
- n) Potential adverse effects or side effects from the use of the medical device, under normal conditions. These are potential undesirable and serious outcomes (death, injury, or serious adverse events) to the patient/user if the device is used under normal condition.
- o) Alternative therapy for diagnosing, treating, curing or mitigating the disease or condition for which the device is intended. This is a description of any alternative practices or procedures to support its intended use. For example, for a drug eluting stent, alternative therapies will include exercise, diet, drug therapy, percutaneous coronary interventions (e.g. balloon angioplasty, atherectomy and bare metal stenting) and coronary artery bypass graft surgery. This does not include any treatment practices or procedures that are considered investigational.

- p) Materials to describe their physical properties to the extent necessary to demonstrate conformity with the relevant Essential Principles. The information shall include:
- i. List of materials of the medical device making either direct (e.g. with the mucous membrane) or indirect contact (e.g., during extracorporeal circulation of body fluids) with a human body;
  - ii. Complete chemical, biological and physical characterization of the materials of the medical device making either direct (e.g. mucous membrane) or indirect contact (e.g., during extracorporeal circulation of body fluids) with a human body;
  - iii. For medical devices intended to emit ionising radiation, information on radiation source (e.g. radioisotopes) and the material used for shielding of unintended, stray or scattered radiation from patients, users and other persons shall be provided.
- q) Other relevant specifications and descriptive information which include the functional characteristics and technical performance specifications and other important descriptive characteristics which have not been detailed out above but it is necessary to demonstrate conformity with the relevant Essential Principles (for example, the biocompatibility category for the finished device).

#### **4.4.4 Manufacturer information:**

##### **4.4.4.1 Manufacturing process**

Manufacturing process for the device should be provided in the form of a list of resources and activities that transform inputs into the desired output.

EXAMPLE The manufacturing process should include the appropriate manufacturing methods and procedures, manufacturing environment or condition, and the facilities and controls used for the manufacturing, processing, packaging, labelling, storage of the device. Sufficient detail shall be provided to enable a person generally familiar with quality systems to judge the appropriateness of the controls in place. A brief summary of the sterilization method and processing should be included, if any. Detailed proprietary information on the manufacturing process is not required. The information may be presented in the form of a process flow chart showing an overview of production, controls, assembly, final product testing and packaging of the finished medical device.

If multiple facilities are involved in the manufacture of the medical device, the manufacturing activities carried out at each site should be clearly identified and the applicable information (e.g. QMS certificates issued by an accredited third-party inspection body) for each facility shall be submitted.

For addition of new sites for the same product, manufacturer/ contract manufacturer shall inform the Authority of such change.

If the manufacturing process of a product consists of a number of sub-assembly processes, the manufacturing sites where each of these sub-assembly processes are carried out shall be identified, and the relationship between these processes shall be shown; or if multiple sites manufacture the same product, each of these sites shall be identified.

The sites (including contract manufacturers) where design and manufacturing activities are performed shall be identified. Quality Management System certificates are to be provided for the design and manufacturing sites (including contract

manufacturers) as an annex to the CSDT submission. Firms that manufacture or process the device under contract to the manufacturer may elect to submit all or a portion of the manufacturing information applicable to their facility directly to the Regulatory Authority in the form of a master file. The manufacturer/ contract manufacturer should inform these contractors of the need to supply detailed information on the device. However, it is not the intent of this section to capture information relating to the supply of sub-components (e.g. printed circuit boards, motors, compressors, batteries) that contributes towards the manufacture of the finished device itself except in cases where the components are part of a medical device system (e.g. femoral stem and acetabular cups of a hip implant system, tubes and connectors for IV set).

#### **4.4.5 Declaration of Conformity**

**4.4.5.1** The DoC shall contain the following information:

- a) Name and address of manufacturer/ contract manufacturer.
- b) An attestation that each device that is subjected to the declaration:
  - i. has been classified according to the classification rules as specified in First Schedule on Rules of Classification of Medical Device; and
  - ii. conforms to requirements specified in the CSDT as submitted.
- c) Particulars of medical device as explained in Table 4 to identify the device to which the DoC applies.
- d) Date from which the Declaration of Conformity for Contract Manufacturer is valid.
- e) 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.
- f) Attestation on the responsibility and acknowledgement on the false declaration.
- g) The name, position, and signature of the top management or person responsible who has been authorised to complete the Declaration of Conformity on the contract manufacturer's behalf.

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.

**Table 4 Explanation on the information/ particulars required in the DoC**

<b>Particulars</b>	<b>Explanation</b>
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. (please list all assigned name for the same medical device).	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 /Contract Manufacturer.	The name of manufacturer /contract manufacturer of the medical device.
Manufacturing site.	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 (if available).	The registration number issued or pre-market approval code assigned by the Authority from GHTF founding members.

**4.4.6** Any additional information, particulars or documents required by the authority shall be provided by the applicant within 90 days from the date of request by the Authority. Inability of the applicant to produce documents when requested by the Authority may result in the cancellation of the application and applicant shall apply new CFS/MC/CFS EO application.

NOTE All periods are in calendar days unless specified as working days.

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

**4.4.8** For additional brand of the same medical device not listed in the initial CFS/MC/CFS EO application, a Declaration letter shall be submitted together with Letter of Authorisation from different manufacturer to the Authority (refer to Annex B for Declaration of Medical Devices Intended for Certificate of Free Sale application for Manufacturer/ Contract Manufacturer Template and Annex C for Letter of Authorisation for Contract Manufacturer Template).



## 5. Issuance of Certificate of Free Sale (CFS), Manufacturing Certificate (MC) or Certificate of Free Sale for Export Only (CFS EO)

The Authority may issue certificate upon satisfactory review of all documents provided as specified required in Table 1, Table 2 and Table 3 respectively and subject to payment of the fees in Table 5.

## 6. Fees

Please refer below for the applicable fees.

- a) Application fee: RM250.00. (Applicable for CFS EO only)
- b) Certificate fee
  - i. Certificate fee is as per Table 5.

**Table 5 Certificate fee**

No	Validity	Fee (RM)
1	2 years	100
2	5 years	300
<ul style="list-style-type: none"> <li>- Calculation is based per number of countries requested.</li> <li>- Certificate is inclusive of 1 attachment. Additional pages will be charged RM5.00 per page. Each attachment will list up to 25 medical devices.</li> <li>- Certificate will be issued based on per country.</li> </ul>		

- ii. Example of calculation:

**Table 6 Example of CFS issuance fee calculation (CFS EO+ CFS + MC)**

No	Application	Calculation
<b>1.</b>	<b>CFS / MC</b>	
i.	2 Countries, 100 medical devices 1 registration number 1 copy of certificate Validity 2 years  (25 medical devices per attachment thus require 4 attachments)	25 medical devices per attachment thus require 4 attachments (complimentary 1 attachment).  RM200 (2 Countries x RM100, 2 years) + RM15 (3 Attachments x RM 5) = RM 215
ii.	2 Countries, 2 medical device registration number 2 copy of certificate Validity 5 years	[RM600 (2 Countries x RM300, 5 years) + RM600 (2 registration numbers x RM300, 5 years)] x 2 Copies = RM 2400
<b>2.</b>	<b>CFS EO</b>	
i.	1 Country 100 medical devices 1 copy of certificate	25 medical devices per attachment thus require 4 attachments. (complimentary 1 attachment).

	Validity 2 years	RM 250 (application fee) + RM 100 (2 years validity) + RM15 (Attachment) = RM 365
ii.	1 Country 100 medical devices 2 copies of certificate Validity 2 years	25 medical devices per attachment thus require 4 attachments. (complimentary 1 attachment).  RM 250 (application fee) + RM 100 (2 years validity) + RM15 (Attachment) = RM 365 for 1 CFS  For 2 copies: RM 250 (application fee) + (RM 120 x 2) = RM 485
iii.	2 Countries 1 medical device 1 copies of certificate Validity 5 years	RM 250 (application fee) + [RM 300 (Validity 5 years) x 1 (Attachment) x 1 (copy) x 2 (countries)] = RM 850

- c) Additional certificates may be issued upon request subject to payment of applicable CFS certificate fees.

## 7. Amendments of Application

Once the certificate is issued, no amendments is allowed, and a new application must be made. The information in the certificate will be according to the information submitted in the certificate application.

Any errors to the certificate issued shall be notified by the applicant within 90 days from the date of issuance.

**Annex A**  
(normative)

**Attestation Template**

Name and Address of Manufacturer/ Contract Manufacturer  
(Please print on Company Letterhead)

Medical Device Authority

Date:

Dear Sir,

**Attestation by manufacturer/ contract manufacturer for CFS application**

I, <Name of Top Management>, <ID>, hereby attest that we are the manufacturer/ contract manufacturer for the medical device in this CFS application, and the information provided in this application and in any attached documentation is/ are accurate, correct, complete and current to this date.

I hereby attest that this/ these device(s) have the objective evidence that the medical device meets the Essential Requirements for Safety and Performance.

I hereby attest that there are no misleading claims made relating to the quality, safety and performance of the medical device.

I understand and acknowledge that it is an offence to make, sign or furnish any declaration, or other documents which is untrue, inaccurate or misleading.

Yours Sincerely,

Signature :

Position :

Official Stamp :

Date :

**Annex B**  
(normative)

**Declaration of Medical Devices Intended for Certificate of Free Sale  
application for Manufacturer/ Contract Manufacturer Template**

[To be printed on Company Letterhead of Manufacturer /Contract Manufacturer]

Chief Executive  
Medical Device Authority  
Ministry of Health Malaysia

Dear Sir/Madam,

**Subject: Declaration of Medical Devices Intended for Certificate of Free Sale  
application**

We, the undersigned, <Name of Company>, declares the following:

<b>Medical Device Details</b>		
No	Generic Name of Medical Device and Brand	Is same as per medical device under CFS certificate No.
1		
2		
3		
4		
<b>Declaration by applicant</b>		
<p>As senior official of the manufacturer/ contract manufacturer,</p> <ul style="list-style-type: none"> <li>- I further declare the medical devices applied for the CFS application are the same as per the medical device in CFS certificate number/ above.</li> <li>- I hereby declare that the information listed in the table is complete and accurate.</li> <li>- I fully understand and acknowledge that it is an offence to make, sign or furnish any declaration, certificate or other document which is untrue, inaccurate or misleading.</li> </ul>		

[Signature]  
[Full Name and Title of Company Representative]  
[Company stamp]  
[Date]

**Annex C**  
(normative)

**Letter of Authorisation for Contract Manufacturer Template (if applicable)**

[To be printed on Company Letterhead of Manufacturer]

Chief Executive  
Medical Device Authority  
Ministry of Health Malaysia

Dear Sir/Madam,

**Subject: Letter of Authorisation for [name of contract manufacturer]**

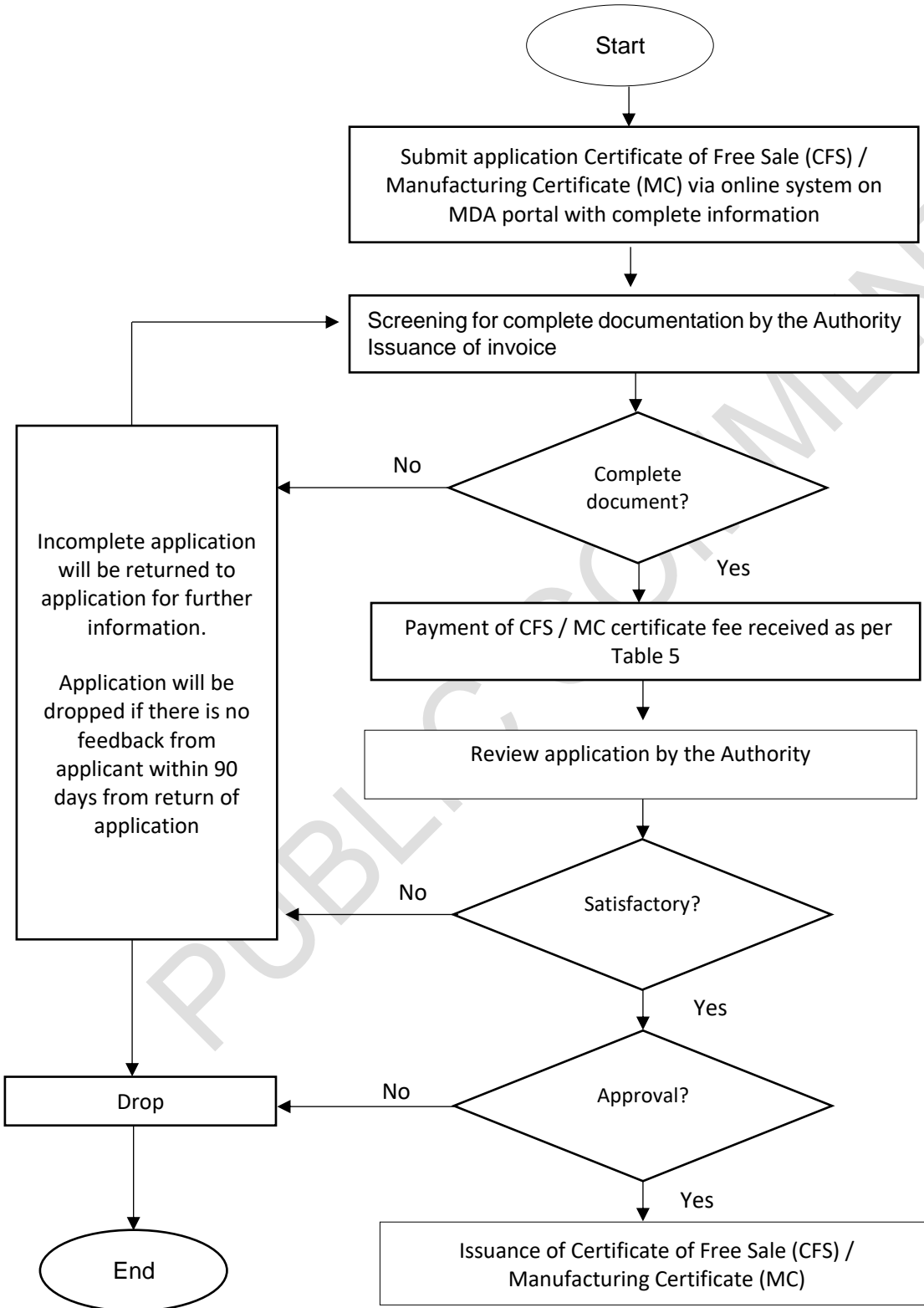
We, the undersigned, <Name of Manufacturer>, as the Manufacturer of the medical device listed in below table, hereby authorize [contract manufacturer name (registration Number) and address], as the contract manufacturer for the medical devices:

Medical Device Details	
No	Generic Name of Medical Device and Brand
1	
2	
3	
4	
Declaration by Manufacturer	
<ul style="list-style-type: none"> <li>- We also authorise [name of contract manufacturer] to make declarations and to submit documents on our behalf, regarding the above medical devices, in support of this application.</li> <li>- We undertake to provide all the necessary support and assistance to the contract manufacturer as may be required to any matter involving the medical devices listed.</li> <li>- We agree to furnish and assist the Medical Device Authority with any request for information on the above medical devices.</li> </ul>	

[Signature]  
[Full Name and Title of Company Representative]  
[Company stamp]  
[Date]

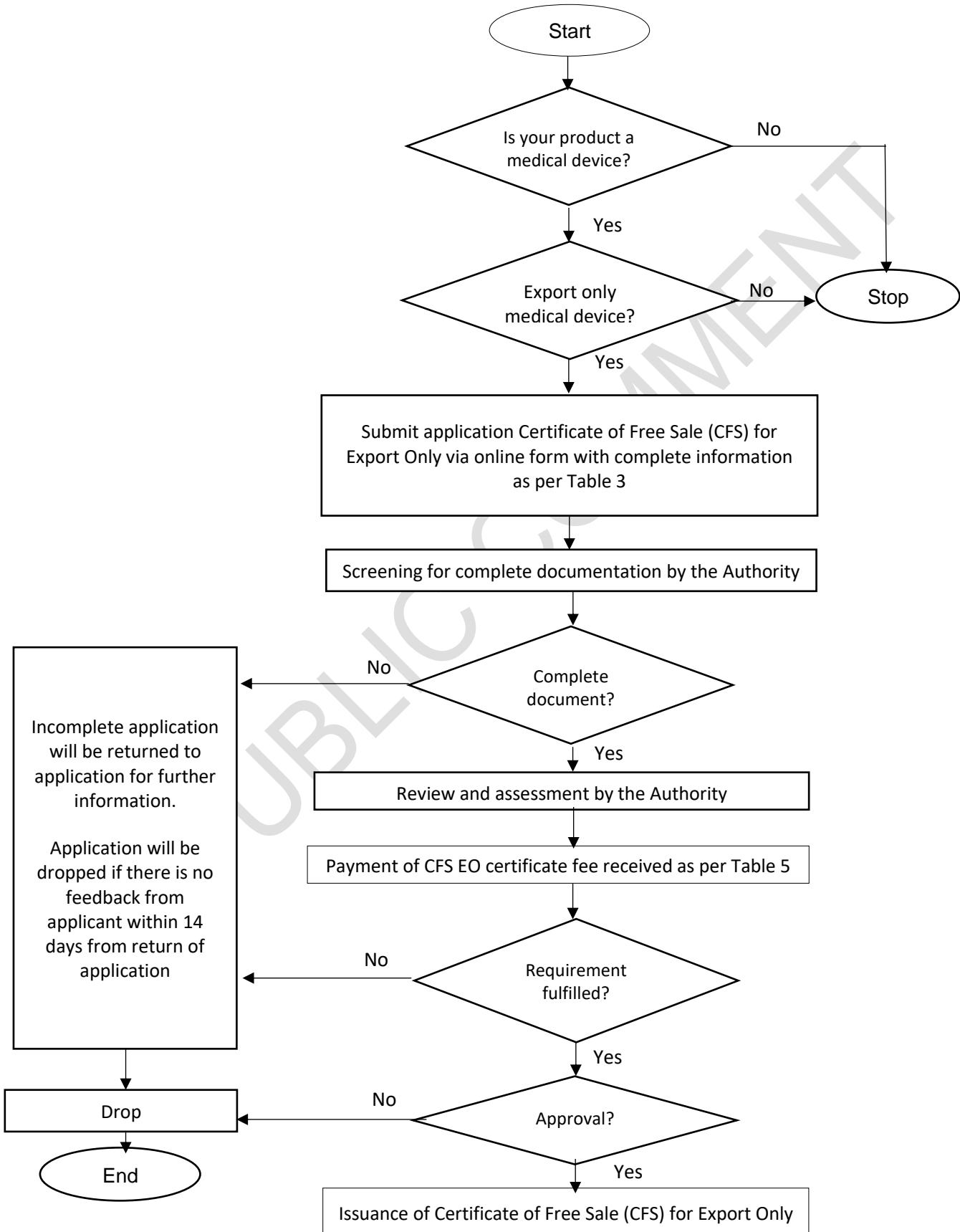
**Annex D**  
(informative)

**Flowchart for Application of Certificate of Free Sale (CFS) or Manufacturing Certificate (MC)**



**Annex E**  
(informative)

**Flowchart for Application of Certificate of Free Sale for Export Only (CFS EO)**



**ANNEX F**  
(informative)

**Summary of Documents Required for CFS, MC and CFS EO**

Documents	Certificate of free sale	Manufacturing Certificate (export only manufacturer)	Manufacturing Certificate (OEM manufacturer)	CFS Export Only
Registrar of Companies (ROC) certificate of applicant	Yes	Yes	Yes	Yes
A copy of establishment licence	Yes	Yes	Yes	If applicable
Proof of medical device registration (Notification letter/Acknowledgement letter/Registration certificate)	Yes	Yes	Not applicable	Not applicable
Medical device list	Yes	Yes	Not applicable	Yes
Letter of declaration as OEM	Not applicable	Not applicable	Yes	Yes
Brochure	No	No	Yes	Yes
Export Only Notification Letter	Not applicable	Not applicable	Not applicable	Yes
CFS Export Only form	Not applicable	Not applicable	Not applicable	Yes
Declaration of Conformity	Not applicable	Not applicable	Not applicable	Yes
Attestation	Not applicable	Not applicable	Not applicable	Yes
List of Configurations of Medical Device	Not applicable	Not applicable	Not applicable	Yes
Declaration of Medical Devices Intended for CFS application if brand is different from Notification Export Only (if applicable)	Not applicable	Not applicable	Not applicable	If applicable
Letter of Authorization for Contract Manufacturer (if applicable)	Not applicable	Not applicable	Not applicable	If applicable
ISO 13485 QMS certificate	Not applicable	Not applicable	Not applicable	Yes
Summary of Technical Documentation (CSDT)	Not applicable	Not applicable	Not applicable	Yes
Essential Principal of Safety and Performance (EPSP)	Not applicable	Not applicable	Not applicable	Yes
Pre-market Approval	Not applicable	Not applicable	Not applicable	Yes
Post Market Vigilance History	Not applicable	Not applicable	Not applicable	Yes
Manufacturing Process	Not applicable	Not applicable	Not applicable	Yes



**Annex G**  
(informative)

**Medical device(s) list**

- a) REMINDER: Please upload only one (1) attachment of product list in one (1) CFS/MC application.
- b) 1 application of CFS/MC is limited to **25 registration Number and Notification ID No.** (If more than 25 registration No and Notification No. applicant must make new application.
- c) The medical device in 1 application form must be from same manufacturer. If the manufacturer is different, applicant must apply in other application form.
- d) For a registered medical device, please fill the details as accordance to your registration certificate or notification letter.
- e) The Medical Device(s) list must be submitted in **Word Doc.** Other format will be rejected.
- f) Please check first with the destination country to find out if you need the certificate and the required details.

**1) Please choose of validity required (write Yes in the requested validity, choose only one)**

<b>2 years</b>  Payment based on <b>RM 100</b> per registration number / Notification ID number / country for 1 certificate inclusive of 1 attachment. Additional pages will be charged RM5.00 per page.	E.g Yes
<b>5 years</b>  Payment based on <b>RM 300</b> per registration number / Notification ID number / country for 1 certificate inclusive of 1 attachment. Additional pages will be charged RM5.00 per page.	-

**2) Please list the medical device name or brand and the registration number /Notification ID No. for the medical device name or brand.**

For applicant who applied for MC (OEM manufacturer), the section registration number /Notification ID No. is not applicable.

NO	MEDICAL DEVICE NAME / BRAND	REGISTRATION NO. / NOTIFICATION ID NO.
1		
2		
3		
4		
5		
6		
7		
8		

## Annex H (normative)

### Medical Device Category

Code	Scope expression
<b>(1) MEDICAL DEVICES, NON-ACTIVE</b>	
<b>MD 0100 GENERAL NON-ACTIVE, NON-IMPLANTABLE MEDICAL DEVICES</b>	
MD 0101	Non-active devices for anaesthesia, emergency and intensive
MD 0102	Non-active devices for injection, infusion, transfusion and dialysis
MD 0103	Non-active orthopaedic and rehabilitation devices
MD 0104	Non-active medical devices with measuring function
MD 0105	Non-active ophthalmologic devices
MD 0106	Non-active instruments
MD 0107	Contraceptive medical devices
MD 0108	Non-active medical devices for disinfecting, cleaning, rinsing
MD 0109	Non-active devices for in vitro fertilisation (IVF) and assisted
<b>MD 0200 NON-ACTIVE IMPLANTS</b>	
MD 0201	Non-active cardiovascular implants
MD 0202	Non-active orthopaedic implants
MD 0203	Non-active functional implants
MD 0204	Non-active soft tissue implants
<b>MD 0300 DEVICES FOR WOUND CARE</b>	
MD 0301	Bandages and wound dressings
MD 0302	Suture material and clamps
MD 0303	Other medical devices for wound care
<b>MD 0400 NON-ACTIVE DENTAL DEVICES AND ACCESSORIES</b>	
MD 0401	Non-active dental equipment and instruments
MD 0402	Dental materials
MD 0403	Dental implants
<b>(2) MEDICAL DEVICES, ACTIVE</b>	
<b>MD 1100 GENERAL ACTIVE MEDICAL DEVICES</b>	
MD 1101	Devices for extra-corporal circulation, infusion and haemopheresis
MD 1102	Respiratory devices, including hyperbaric chambers for oxygen therapy, inhalation anaesthesia
MD 1103	Devices for stimulation or inhibition
MD 1104	Active surgical devices

<b>Code</b>	<b>Scope expression</b>
<b>MD 1105</b>	<b>ACTIVE OPHTHALMOLOGIC DEVICES</b>
MD 1106	Active dental devices
MD 1107	Active devices for disinfection and sterilisation
MD 1108	Active rehabilitation devices and active prostheses
MD 1109	Active devices for patient positioning and transport
MD 1110	Active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART)
MD 1111	Software
<b>MD 1200</b>	<b>DEVICES FOR IMAGING</b>
MD 1201	Imaging devices utilising ionizing radiation
MD 1202	Imaging devices utilising non-ionizing radiation
<b>MD 1300</b>	<b>MONITORING DEVICES</b>
MD 1301	Monitoring devices of non-vital physiological parameters
MD 1302	Monitoring devices of vital physiological parameters
<b>MD 1400</b>	<b>DEVICES FOR RADIATION THERAPY AND THERMOTHERAPY</b>
MD 1401	Devices utilising ionizing radiation
MD 1402	Devices utilising non-ionizing radiation
MD 1403	Devices for hyperthermia / hypothermia
MD 1404	Devices for (extracorporal) shock-wave therapy (lithotripsy)
<b>(3) ACTIVE IMPLANTABLE MEDICAL DEVICES</b>	
<b>AIMD 0100</b>	<b>GENERAL ACTIVE IMPLANTABLE MEDICAL DEVICES</b>
AIMD 0101	Active implantable medical devices for stimulation /inhibition
AIMD 0102	Active implantable medical devices delivering drugs or other substances
AIMD 0103	Active implantable medical devices substituting or replacing organ functions

**Annex I**  
(normative)

**Submission Template for Medical Devices**

**LIST OF CONFIGURATIONS FOR MEDICAL DEVICE FOR CFS APPLICATION**

**Guidelines on completing the table below:**

1. For the “Name as per Device Label” column:

(a) For a medical device family, list the names of the constituent members in this column. Enter the identifier associated with each constituent member in the “Identifier” column.

(b) For a medical device set, list the names of the constituent medical devices in this column. Enter the identifier associated with each constituent medical device in the “Identifier” column.

(c) For a medical device system, list the names of every constituent component in this column. Enter the identifier associated with each constituent component in the “Identifier” column.

(d) For an IVD test kit, list the names of every constituent reagent and article in this column. Enter the identifier associated with each constituent reagent and article in the “Identifier” column.

NOTE Please use the "list of configs (IVD CLUSTER)" worksheet for an IVD cluster.

2. For the “Identifier” column, identifier refers to a unique series of letters or numbers or any combination of these or a bar code that is assigned to a medical device by the manufacturer and that identifies it and distinguishes it from similar devices. Examples of an identifier for a device are a barcode, catalogue, model or part number.

3. For the “Brief Description of Item” column, give a brief description of the key distinguishing attributes or specifications of each item. Examples of a brief description of a constituent member of a family include the following:  
A system which consists of the same parameters but different throughput of the sample or reagent with different packaging volume.

4. A list of configurations is to be provided with each FAMILY/SET/SYSTEM medical device application.

<b>Name of Medical Device SINGLE/FAMILY/SET/SYSTEM:</b>	LATEX SURGICAL GLOVES POWDERED FREE
<b>Proposed Grouping for Medical Device (SINGLE/FAMILY/SET/SYSTEM):</b>	FAMILY

No	Components of Medical Device SINGLE/FAMILY/SET/SYSTEM				
	Name as per Device Label	Permissible Variant	Details on Permissible Variant	Identifier	Brief Description of Item
Example 1	LATEX SURGICAL GLOVES POWDER FREE. List of brands for this medical device: Brand A, Brand B, Brand C.	Powder content, size	Powder free, size S, M, L, XL	123	Powder free latex surgical gloves with sizes S, M, L, XL
Example 2	POWDERED LATEX SURGICAL GLOVES. List of brands for this medical device: Brand A, Brand D, Brand E.	Powder content, size	Powdered, size S, M, L, XL	124	Powdered latex surgical gloves with sizes S, M, L, XL
Example 3	Colored latex surgical gloves powder free. List of brands for this medical device: Brand A, Brand B, Brand C.	Powder content, size, color	Powder free, size S, M, L, XL, red, blue, green	125	Powder free latex surgical gloves with sizes S, M, L, XL and color choices of red, blue and green

# **MEDICAL DEVICE AUTHORITY**

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## **MINISTRY OF HEALTH, MALAYSIA**

### **Contact Information:**

**Medical Device Authority**  
Ministry of Health Malaysia  
Level 6, Prima 9, Prima Avenue II  
Block 3547, Persiaran APEC  
63000 Cyberjaya, Selangor  
MALAYSIA  
T: (03) 8230 0300  
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