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MEDICAL DEVICE GUIDANCE DOCUMENT

REQUIREMENTS FOR APPLICATION OF CERTIFICATE OF FREE SALE (CFS) FOR EXPORT ONLY 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, and/or to facilitate their business endeavour.

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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REQUIREMENTS FOR APPLICATION OF CERTIFICATE OF FREE SALE (CFS) FOR EXPORT ONLY 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 CFS for export only medical device.

2 Scope and application

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

This document applies to any person who wish to apply for CFS 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 purposes of this document, the terms and definitions in Act 737, Medical Device Regulations 2012 and the following 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

Means any person who performs the activity of manufacture.

[Source: ASEAN Medical Device Directive (AMDD)]

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@mdb.gov.my to determine the classification of the products. The guidance document and form are available to be downloaded at MDA website www.mdb.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

The applicant who require CFS shall submit the completed 'CFS application for export only medical device exempted from registration form' together with relevant documents by email to cfs@mdb.gov.my. Please make sure to include "CFS application for export only medical device exempted from registration form" on the e-mail titles when sending e-mails to Authority. The form is available to be downloaded at MDA website www.mdb.gov.my.

4.4.1 The information and documentation required for application of CFS for for export only medical device exempted from registration are as per listed in Table 1.

Table 1: Requirements for CFS application for export only medical device exempted from registration

No	Requirements	Explanation
a)	Acknowledgement on Notification for export only medical device.	Please provide acknowledgement on Notification by applying the "Notification for export only medical device".
b)	**General information**	
	i. Is the medical device for export only?	Please tick the appropriate box.
	ii. Does the medical device contain any active ingredient, poison or drug?	Please tick the appropriate box. If yes, kindly attach information on the active ingredient, poison or drug.
	iii. Type of medical device.	Please tick the appropriate box.
	iv. Class of medical device.	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.
	v. Classification rules.	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. 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.

No	Requirements	Explanation
	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 A**.
	vii. Medical device name.	Please provide the general name of the medical device as per described in the brochure/ catalogue/ label/ product specification document. Example: powder free latex examination glove, natural rubber latex male condom, automatic operated disposable lancet, peripheral vascular catheter.
	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 any active ingredient/ poison/ drug).	Please provide the information on 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)	**Quality Management System (QMS) Certificate** – 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)	**Grouping.**	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

No	Requirements	Explanation
		2012 and further elaborated in the Guidance Document on Product Grouping, MDA/GD/0005.
e)	**Summary of technical documentation (Common Submission Dossier Template, CSDT).** (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:	
	- Summary of clinical evidence (consist of objective, method, result, discussion, conclusion).	Not applicable.
	- Summary of Pre-Clinical Test (consist of objective, method, result, discussion, conclusion).	Not applicable.
	- Use of existing bibliography.	Not applicable.
	- Relevant safety and validation report.	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 - Sample of label shall be provided for medical device.	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 D).
	vi. Risk Analysis.	Not applicable.
	vii. Manufacturer information (manufacturing process).	Refer to Clause 4.4.4.
f)	**Premarket approval** (Certificate/ report/ self-declare).	Premarket approval including from importing countries (if available) shall be submitted.
g)	**Post-market vigilance history** (within the last 5 years). - Manufacturer information; and	Manufacturer/ Contract manufacturer shall provide information on Post-market vigilance history of the medical device.

No	Requirements	Explanation
	- Corrective Action Report (CAR); or - Corrective Action and Preventative Action (CAPA) (medical device under registration); or - Any ongoing Post-Market Issues.	A declaration letter shall be submitted if there are no on-going post market issues.
h)	**Declaration of Conformity (DoC)** for Manufacturer/ contract manufacturer.	It is the responsibility of the manufacturer /contract manufacturer for preparing and signing the DoC as 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 C.

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 application. This is to be provided using the format as in Annex D.

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 2 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 2. Explanation on the information/ particulars required in the DoC

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. (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 application.

Note: All periods are in calendar days unless specified as working days.

4.4.7 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.

4.4.8 For additional brand of the same medical device not listed in the initial CFS application, a **Declaration letter needs to be submitted** together with **Letter of Authorisation** from different manufacturer to the Authority (refer to **Annex E** for Declaration of Medical Devices Intended for Certificate of Free Sale application for export only medical device template and **Annex F** for Letter of Authorisation for Contract Manufacturer Template).

5 Issuance of Certificate of Free Sale (CFS)

The Authority may, after considering the application for CFS in Clause 4 and upon satisfactory review of all documents provided as required in Table 1 and subject to payment of the fees in Table 3, issue an approval for issuance of CFS.

6 Fees

Please refer below for the applicable fees.

a) Application fee: RM250.00.

b) CFS certificate fee

i. CFS certificate fee is as per Table 3.

Table 3: CFS certificate fee

No	Validity	Fee (RM)
1	2 years	100
2	5 years	300
- Calculation is based per number of country requested. - Certificate is inclusive of 1 attachment. Additional pages will be charged RM5.00 per page. Each attachment will list up to 25 medical devices. - Certificate will be issued based on per country.		

ii. Example of calculation:

Table 4: Example of CFS issuance fee calculation

No	Application	Calculation
1	1 Country 100 medical devices 1 copy of certificate Validity 2 years	25 medical devices per attachment thus require 4 attachments. (RM 5 x 4 attachment = RM20); RM 250 (application fee) + RM 100 (2 years validity) + RM20 (Attachment) = RM 370
2	1 Country 100 medical devices 2 copies of certificate Validity 2 years	25 medical devices per attachment thus require 4 attachments. (RM 5 x 4 attachment = RM20); RM 250 (application fee) + RM 100 (2 years validity) + RM20 (Attachment) = RM 370 for 1 CFS For 2 copies: RM 250 (application fee) + (RM 120 x 2) = RM 490
3	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.

Annex A
(normative)

Medical Device Category

Code	Scope expression
(1) MEDICAL DEVICES, NON-ACTIVE	
MD 0100: GENERAL NON-ACTIVE, NON-IMPLANTABLE MEDICAL DEVICES	
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
MD 0200: NON-ACTIVE IMPLANTS	
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
MD 0300: DEVICES FOR WOUND CARE	
MD 0301	Bandages and wound dressings
MD 0302	Suture material and clamps
MD 0303	Other medical devices for wound care
MD 0400: NON-ACTIVE DENTAL DEVICES AND ACCESSORIES	
MD 0401	Non-active dental equipment and instruments
MD 0402	Dental materials
MD 0403	Dental implants
(2) MEDICAL DEVICES, ACTIVE	
MD 1100: GENERAL ACTIVE MEDICAL DEVICES	
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

Code	Scope expression
MD 1105	Active ophthalmologic devices
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
MD 1200: DEVICES FOR IMAGING	
MD 1201	Imaging devices utilising ionizing radiation
MD 1202	Imaging devices utilising non-ionizing radiation
MD 1300: MONITORING DEVICES	
MD 1301	Monitoring devices of non-vital physiological parameters
MD 1302	Monitoring devices of vital physiological parameters
MD 1400: DEVICES FOR RADIATION THERAPY AND THERMO THERAPY	
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)
(3) ACTIVE IMPLANTABLE MEDICAL DEVICES	
AIMD 0100: GENERAL ACTIVE IMPLANTABLE MEDICAL DEVICES	
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 B
(normative)

Declaration of Conformity for Manufacturer /Contract Manufacturer CFS Application Template

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

I, <please provide the name of top management/ person responsible/ name of manufacturer /contract manufacturer>, hereby declare that the below mentioned medical device:

(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.

(A) Particulars of medical device:

Generic name:
Specified name:
Brand (please list all Brands for the same medical device):
Manufacturer /Contract Manufacturer:
Manufacturing site:
Risk-based classification:
Classification rule:
(Note: according to First Schedule on Rules of Classification of Medical Device)
GMDN code (if available):
Medical device registration number or any approval code in other country: (if available)

(B) Quality Management System certificate (ISO 13485)
Conformity Assessment Body issuing the certificate:
Certificate number:
Issuance date:
Expiry date:

(C) Standards 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 to make, sign or furnish any declaration, certificate or other document which is untrue, inaccurate or misleading.

Authorised Signatory:

_____
Name/Position

Annex C
(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>, <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 :

Name :

Position :

Official Stamp :

Date :

Annex D
(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: For an IVD cluster, please use the "list of config (IVD CLUSTER)" worksheet.

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.

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

Annex E
(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:

Medical Device Details		
No	*Generic Name of Medical Device and Brand*	*Is same as per medical device under CFS certificate No.*
1		
2		
3		
4		
Declaration by applicant		
As senior official of the manufacturer/ contract manufacturer, - *I further declare the medical devices applied for the CFS application are the same as per the medical device in CFS certificate number above.* - *I hereby declare that the information listed in the table is complete and accurate.* - *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.*		

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

Annex F
(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]

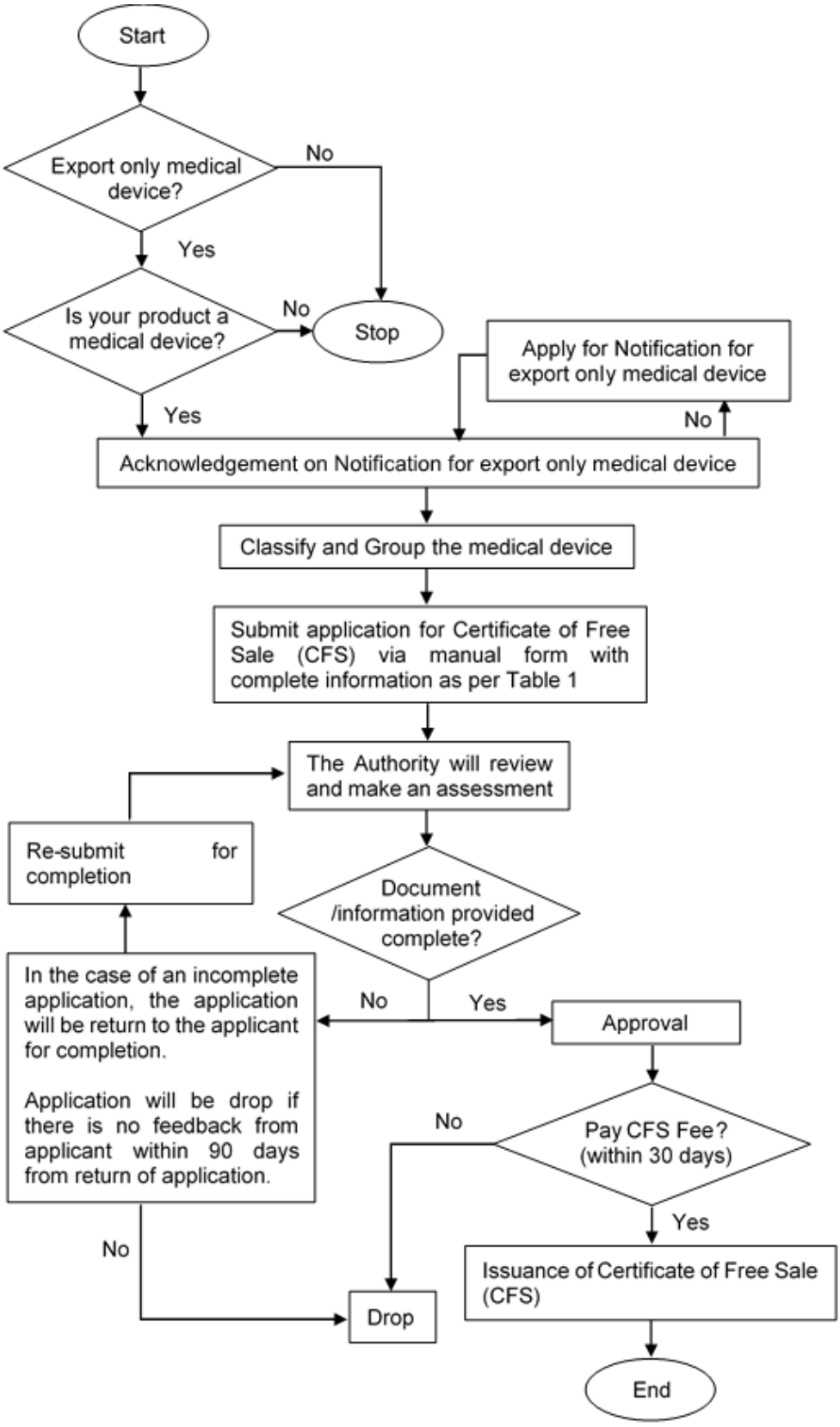
We, the undersigned, <Name of Manufacturer>, as the Manufacturer of the medical device listed in below table, hereby authorize [contract manufacturer name (registration Number) and address], as the contract manufacturer for the medical devices:

Medical Device Details	
No	Generic Name of Medical Device and Brand
1	
2	
3	
4	
Declaration by Manufacturer	
- 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. - 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. - We agree to furnish and assist the Medical Device Authority with any request for information on the above medical devices.	

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

Annex G
(informative)

APPLICATION OF CERTIFICATE OF FREE SALE (CFS) FOR EXPORT ONLY MEDICAL DEVICE FLOWCHART



MEDICAL DEVICE AUTHORITY

MINISTRY OF HEALTH, MALAYSIA

Contact Information:

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