CLASS A NEW AND RE-REGISTRATION APPLICATION VIA MEDC@ST

Class A medical device (new and re-registration) applications can be submitted directly to MDA via MeDC@St. The submission requirements for a Class A medical device in MeDC@St are stipulated in **Appendix 1** and are based on the information requested in the MeDC@St application form. A summary of Class A medical device requirements is in the **Table** below:

Section	Medical Device Registration Form Class A	New	Re-Reg
1	Medical device classification	√	
2	Determine if the product is a medical device	√	
3	Medical device general information	√	
4	Medical device grouping	√	
5	Additional requirements	√ if applicable	
6	Manufacturer information	√	√ updated QMS
7	Pre-market clearance / pre-market approval	√ if applicable	√ if applicable
8	Labelling	√	√ updated label
9	Post-market surveillance and vigilance	√	√ updated PMS
10	Declaration of conformity	√	√ updated DoC

APPENDIX 1: SUBMISSION GUIDE FOR CLASS A MEDICAL DEVICE REGISTRATION APPLICATION IN MeDC@St FOR NEW AND RE-REGISTRATION APPLICATION

The guides represent the minimum information/documentation that the manufacturer shall prepare and submit in the system. Irrespective of the requirements in the table below, MDA has the right to request information or material, or define conditions not specifically described in this document that are deemed necessary for the purpose of regulatory control.

MEDICAL DEVICE REGISTRATION FORM	EXPLANATION/REQUIREMENTS	NEW	RE-REG
SECTION 1: MEDICAL DEVICE CLASSIFICATION			
Medical device risk and classification details	• The risk classification and rule in accordance with the rules of medical device classification as outlined in the First Schedule of MDR 2012 and Guidance Document on the Rules of Classification for General Medical Devices (MDA/GD/0009) or In-Vitro Diagnostic (IVD) Medical Device Classification System (MDA/GD/0001).	√	
Establishment detail	• The establishment shall have a valid license as a local manufacturer or authorised representative (AR) as defined in Section 2 of Act 737 with a valid license number and expiration date. • This information is pre-populated from the establishment license module.	√	
SECTION 2: DETERMINE IF THE PRODUCT IS A MEDICAL DEVICE			
Medical device interpretation, accessory, component	• Determine whether a product is a medical device as defined in Section 2 of Act 737, an accessory or a component. • Accessory means an article that is intended specifically by manufacturers to be used together with a 'parent' medical device to enable that medical device to achieve its intended purpose or to augment or extend the capabilities of that device in fulfilment of its intended use as a medical device. • Component means one of several possibly unequal subdivisions that together constitute the whole medical device to achieve the latter's intended purpose, which may also be known as a part but not a medical device in its own right.	√	
SECTION 3: MEDICAL DEVICE GENERAL INFORMATION			
Medical device name	• The product meets the definition of a medical device under Section 2 of Act 737 and Guidance Document on the Definition of Medical Device (MDA/GD/0006). • The name of a medical device given by its manufacturer that identifies a manufacturer's medical device as distinct from those of other manufacturers, as per device label, IFU, catalogue and brochure. • For re-registration, no changes to existing information unless approved by MDA via a change notification.	√	
Proprietary name / brand	• A brand name is a unique name given by the manufacturer to identify a medical device as a whole product, also known as the trade name. The brand name shall be on the label, DoC and technical documentation. • For re-registration, no changes to existing information unless approved by MDA via a change notification.	√	
Medical device category	• A medical device category is a broad grouping of medical devices that share common characteristics, such as their purpose, type of use (diagnostic, therapeutic, monitoring, etc.), or the area of the body they affect.	√	

MEDICAL DEVICE REGISTRATION FORM	EXPLANATION/REQUIREMENTS	NEW	RE-REG
Is the medical device meant for export only?	• The importation, exportation, or placement of a medical device in the Malaysian market requires the medical device to be registered under Act 737. Medical Device (Exemption) Order 2024 states that medical devices for the purpose of export only are exempted from registration requirements and shall make an application for an exemption to the Authority as outlined in the Guidance Document on Notification on Export only Medical Device (MDA/GD/0051).	√	
Description of medical device	• The detailed description of the medical device which includes how the device functions, the basic scientific concepts that form the fundamentals for the device, the component materials and accessories used in its principles of operation as well as packaging. This should include a complete description of each functional component, material or ingredient of the device. • For re-registration, no changes to existing information unless approved by MDA via a change notification.	√	
Common intended use of medical device	• The intended use of the medical device, 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, as stated in: a. the information provided with the device, or b. the instructions for use of the device, or c. any advertising material applying to the device. • It shall be consistent with the data in technical documentation including IFU, CSDT, clinical evaluation report and approved intended use in the recognised foreign regulatory authorities or notified bodies. • For re-registration, no changes to existing information unless approved by MDA via a change notification.	√	
HS Code/GMDN Code /Unique device identifier/UMDNS Code	• HS Code (Harmonized System Code) means an internationally standardized system of names and numbers used to classify traded products. • GMDN means 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. • UDI stands for Unique Device Identifier. It is a globally standardized system used to identify and track medical devices throughout their lifecycle, from production to use and eventual disposal. The UDI system enhances patient safety, facilitates post-market surveillance, and improves supply chain efficiency. • UMDNS Code stands for Universal Medical Device Nomenclature System Code. It is a coding system developed to provide a standardized way to identify and classify medical devices and equipment.	√ if applicable	
IFU / Brochure / Product Catalogue	• The IFU is also known as the product insert user or operating manual. Instructions of use including the procedures, methods, frequency, duration, quantity and preparation to be followed for the 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 in other formats/forms. • Brochure/product catalogue is materials that contain product pictorial representation, brand and/or company name and/or logo that do not consist of any product claims or descriptions including catalogues, brochures, flyers, etc. • For re-registration, no changes to existing information unless approved by MDA via a change notification.	√	

MEDICAL DEVICE REGISTRATION FORM	EXPLANATION/REQUIREMENTS	NEW	RE-REG
SECTION 4: MEDICAL DEVICE GROUPING			
Medical device grouping (list of devices)	• The listing based on grouping criteria specified in MDR 2012, and Guidance Document on General Medical Device Grouping (MDA/GD/0005) and Guidance on the Product Grouping for In vitro Diagnostic (IVD) Medical Devices (MDA/GD/0054), including identifier (e.g. bar code, catalogue, model or part number, UDI) and description of device. • For re-registration, no changes to existing information unless approved by MDA via a change notification.	√	
SECTION 5: ADDITIONAL REQUIREMENTS			
Measuring function • Validation report & certificate (conforms to metrological requirement)	• For medical devices with a measuring function where inaccuracy could have a significant adverse effect on the patient, studies demonstrating conformity with metrological requirements shall be provided.	√ if applicable	
Supplied sterile – Sterillization validation report & certificate	• For medical devices supplied sterile, the following information is to be provided: – detailed information of the initial sterilisation validation including bio burden testing, pyrogen testing, testing for sterilant residues (if applicable) and packaging validation. If initial sterilisation validation is not performed, adequate justification must be provided. For example, if reference to the sterilisation validation conducted for another medical device is made for the medical device in the application, the justification for the applicability of the previously conducted validation to the current medical device must be provided. In addition, the initial sterilisation validation report for the reference medical device must be provided; – evidence of the on-going revalidation of the process. Typically, this would consist of arrangements for, or evidence of, revalidation of the packaging and sterilisation processes; – detailed validation information should include the method used, sterility assurance level attained, standards applied, the sterilisation protocol developed in accordance with those standards, and a summary of results; – post-sterilisation functional test on the medical device; – if the sterilant is toxic or produces toxic residuals (e.g. ethylene oxide residues), test data and methods that demonstrate that post-process sterilant and/or residuals are within acceptable limits must be presented.	√ if applicable	
Others: please specify – Any related document	• This section is specifically intended for tests performed to ensure the safety and/or effectiveness of the device that are not addressed in other sections. This should include a description of the purpose of the test, the risk/safety issue the test is addressing; the test methods and results of the test, e.g. biological evaluation test, software validation, stability, certificate of analysis, material safety data sheet, etc.	√ if applicable)	√ if applicable
Active medical device • Validation report / certificate	• Evidence supporting electrical safety, mechanical and environmental protection, and electromagnetic compatibility are to be provided. This should include a summary of the non-clinical evidence, e.g. summary and electrical safety test protocols, reports, certificates (IEC 60601-1 series).	√ if applicable	

MEDICAL DEVICE REGISTRATION FORM	EXPLANATION/REQUIREMENTS	NEW	RE-REG
Contain animal, human, microbial, recombinant origin (IVD) • Package insert containing information on all list of material • Identify of immediate sources of all list material	• Evaluations performed to demonstrate the safety of materials of biological origin (e.g. animal sourced, human sourced material) are to be included. This should include: – a list of all materials of animal, human, microbial and/or recombinant origin used in the medical device and in the manufacturing process of the medical device. This includes animal or human cells, tissues and/or derivatives, rendered non-viable and cells, tissues and/or derivatives of microbial or recombinant origin; – detailed information concerning the selection of sources/donors; – detailed information on the harvesting, processing, preservation, testing and handling of tissues, cells and substances; – process validation results to substantiate that manufacturing procedures are in place to minimise biological risks, in particular, with regard to viruses and other transmissible agents; – full description of the system for record keeping allowing traceability from sources to the finished medical device.	√ if applicable	
SECTION 6: MANUFACTURER INFORMATION			
Legal manufacturer's name and address	• The name and address of the legal manufacturer. • For re-registration, no changes to existing information unless approved by MDA via a change notification.	√	
Quality management system information – QMS standard(s), certificate no., issuance date, expiry date, QMS certificate	• The manufacturer's QMS certificate, issued by a foreign recognised notified body (NB) or regulatory authority (RA) or MDA registered CAB granting the certificate. • Updated copies of ISO 13485 certificates are to be provided from the legal manufacturer or other acceptable QMS – MDSAP, US FDA Quality Systems Regulations or Japan MHLW Ordinance 169 or ISO 9001 (for a class A empty gas cylinder only) • The scope of certification shall be applicable for the device to be registered. • Outsourcing activities shall be addressed in the audit report. An audit report may be requested if deemed necessary. • If the foreign legal manufacturer is not ISO 13485 certified, the ISO 13485 certificate from the OEM manufacturer can be provided, together with the Traceability of Evidence of Conformity Attestation Template for Medical Device Registration Form as a supporting document. • For re-registration, the QMS shall be updated.	√	√ updated QMS
List of manufacturing site – Manufacturing site's name and address, QMS information	• The sites including contract manufacturers where design and manufacturing activities are performed and/or outsourcing of manufacturing activities shall be indicated. • The manufacturing site's QMS certificate shall be provided for the manufacturing sites of the finished devices. • For refurbished devices, the refurbishment process must be covered within the scope of the QMS certificate. • For re-registration, no changes to existing information unless approved by MDA via a change notification.	√ if applicable	

MEDICAL DEVICE REGISTRATION FORM	EXPLANATION/REQUIREMENTS	NEW	RE-REG
SECTION 7: PRE-MARKET CLEARANCE / PRE-MARKET APPROVAL			
• USFDA • Australia TGA • European Union (EU) • Health Canada • Japan MHLW • Non-reference countries	• Providing the pre-market information is optional but advisable to support the application. • MDA may also request the document if deemed necessary.	√ if applicable	√ if applicable
SECTION 8: LABELLING			

Medical device labelling	– The label shall be updated in accordance with the Sixth Schedule of the MDR 2012, Guidance Document on the Requirements of Labelling for Medical Devices (MDA/GD/0026) and other relevant guidance documents specific to the device. This should include:
	  – sample of labels on the device and its packaging, instruction for use, other literature or training materials (such as physician's manual), instructions for installation and maintenance (if applicable), any information and instructions given to the patient, including instructions for any procedure he patient is expected to perform (if applicable).
	  – The details such as device name, identifier, brand name, name & address of the manufacturer/AR, sterile or single-use symbol, an indication of lot number/serial number/expiry date/manufacturing date/ MDA registration number, storage conditions and shelf life information, Bahasa Malaysia translation for home use/self-test device shall be stated on the device label.
	• For re-registration, an updated label shall be provided, with the MDA registration number and AR information.
		√	√ updated label

SECTION 9: POST-MARKET SURVEILLANCE AND VIGILANCE			
• History of previous recalls, reportable adverse incidents, banning in other countries or post market surveillance studies • Application/registration been rejected/suspended in other country (-ies)? • Ongoing post-market issues?	• Include a summary of reportable adverse events and field corrective actions (FCAs), including recalls for the past 3 to 5 years. • For FSCAs that are 'open', provide a description of any analysis and/or corrective and preventive actions undertaken by the manufacturer. • If there is an ongoing adverse event or field safety corrective action for the medical device that has been reported to MDA, provide the MDA reference number. • If there have been no adverse events or FSCAs, including recalls to date, provide an attestation letter from the manufacturer on company letterhead, that there have been no adverse events or FSCAs since the commercial introduction of the device. • For re-registration, an updated PMS shall be provided.	√	√ updated PMS

MEDICAL DEVICE REGISTRATION FORM	EXPLANATION/REQUIREMENTS	NEW	RE-REG
SECTION 10: DECLARATION OF CONFORMITY			
Declaration of Conformity (DoC)	• The manufacturer shall be required to attest that its medical device complies fully with all essential principles for safety and performance and shall draw up an updated DoC in the format as specified in Appendix 3 of the Third Schedule of MDR2012 and Guidance Document on Declaration of Conformity (MDA/GD/0025). The QMS information shall be valid and vertical and horizontal standards shall be stated. • The DoC shall be prepared with the manufacturer's letterhead and signed by the company's top management. • For re-registration, an updated DoC shall be provided.	√	√ updated DoC
Any related information	• Other information not covered under the above sections such as a change notification letter issued by MDA (if any) shall be submitted. If no changes, provide a declaration letter of no change to the device for the last 5 years for re-registration.	√ if applicable	√ if applicable

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