CLASS B, C AND D NEW AND RE-REGISTRATION APPLICATION VIA MEDC@ST

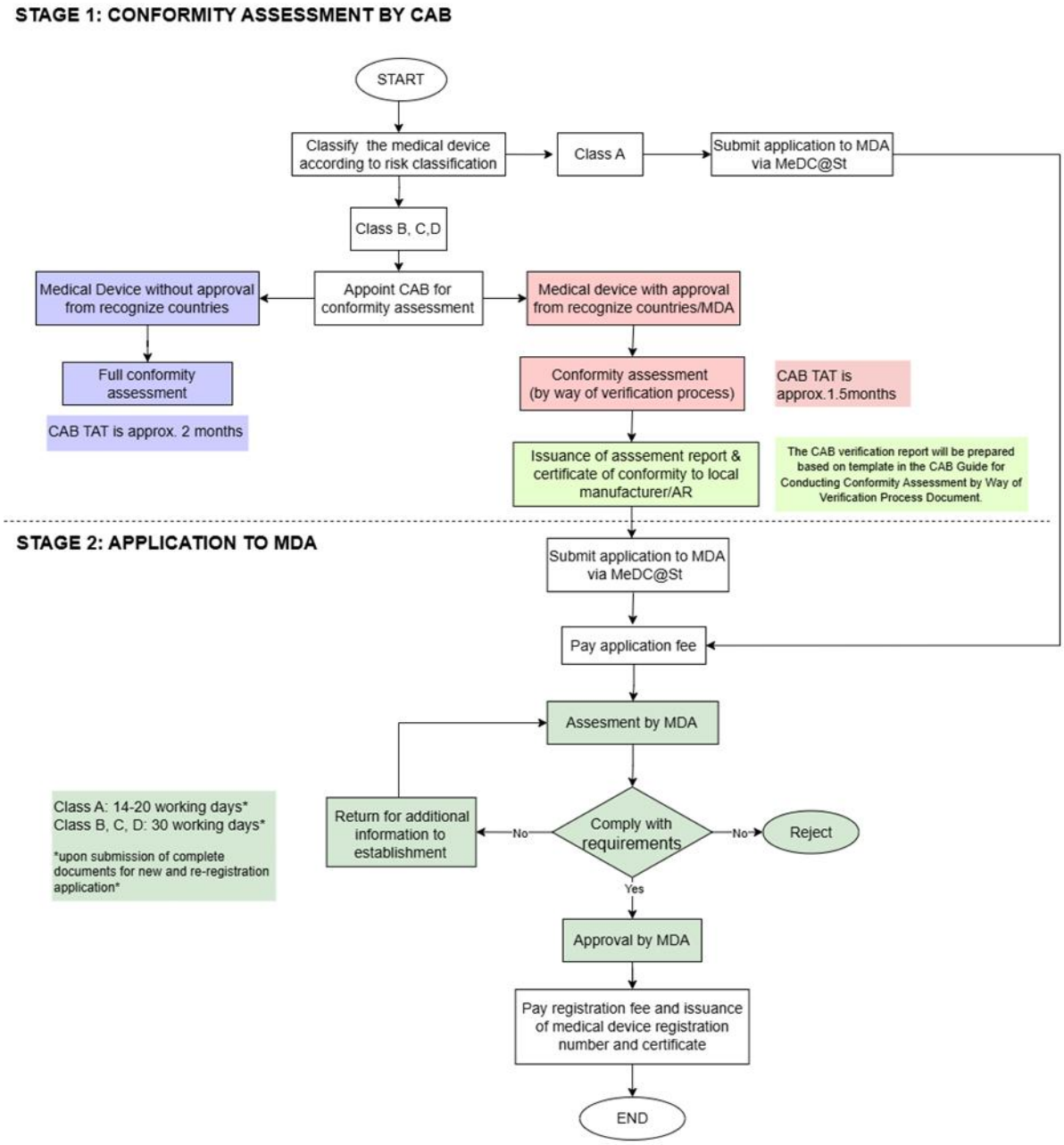

Figure 1: Medical device registration process flow

The report and certificate of conformity assessment shall be submitted as one of the requirements for registration of a medical device. The submission requirements for a Class B, C, and D medical device in MeDC@St are stipulated in **Appendix 1** of this guideline and are based on the information requested in the MeDC@St application form. The same technical dossier and supporting documents that were reviewed by the CAB shall be submitted in soft copy to MeDC@St. English and/or Bahasa Malaysia are the only acceptable languages for the submission of documentation and any related correspondence. A summary of Class B, C, and D medical device requirements is in the **Table** below:

Section	Medical Device Registration Form Class B, C, and D	New	Re-Reg
1	Medical device classification	√	
2	Medical device general information	√	
3	Medical device grouping	√	
4	Common submission dossier template (CSDT)	√	√ updated CER/CPR, label, risk analysis
5	Manufacturer information	√	√ updated QMS
6	Pre-market clearance / pre-market approval	√	√ if applicable
7	Conformity assessment	√	√ updated CAB report & certificate
8	Post-market surveillance and vigilance	√	√ updated PMS
9	Declaration of conformity	√	√ updated DoC

APPENDIX 1: SUBMISSION GUIDE FOR CLASS B, C, AND D FOR CONFORMITY ASSESSMENT BY CAB AND SUBMISSION OF 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			
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: MEDICAL DEVICE GENERAL INFORMATION			
Role of establishment to the medical device	• Role of establishment to the medical device – local manufacturer or authorised representative	√	
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, 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.	√	
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).	√	
Combination product	• The medical device incorporates medicinal substance in an ancillary role as defined in the Guideline for Drug-Medical Device and Medical Device-Drug Combination Products 5th Edition. • If yes, provide an endorsement letter (EL) / acknowledgement receipt (AR) issued by NPRA. If AR is submitted, an EL shall be submitted to MDA within a year from the AR issuance date.	√	

MEDICAL DEVICE REGISTRATION FORM	EXPLANATION/REQUIREMENTS	NEW	RE-REG
Medical device contains any active ingredient, poison or drug	• Indicate whether the medical device contains any formulation, active ingredient, poison or drug. The ingredient, scientific name, ingredient function, quantity and composition percentage information shall be provided. • The template is downloadable from the MeDC@St system. • MDA may seek confirmation from NPRA to confirm that the components does not achieve its primary mode of action by pharmacological, immunological or metabolic action in/on the body.	√	
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.	√	
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.	√	
SECTION 3: MEDICAL DEVICE GROUPING			
Medical device grouping (list of devices)	• The listing is 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.	√	

MEDICAL DEVICE REGISTRATION FORM	EXPLANATION/REQUIREMENTS	NEW	RE-REG
SECTION 4: COMMON SUBMISSION DOSSIER TEMPLATE (CSDT)			
CSDT	• CSDT elements include an executive summary, EPSP, description of the medical device, summary of design verification and validation documents, summary of clinical evidence, labelling, risk analysis and manufacturer information as outlined in the Guidance Documents on the Common Submission Dossier Template (CSDT) for Medical Devices (MDA/GD/0008) and IVD Medical Devices (MDA/GD/0004). • Where there are elements not applicable to the medical device dealt with, the justification for the non-applicability should be provided. • Where such supporting documents are referenced within CSDT, every document must be submitted in full, e.g. all the pages of a document must be submitted. Those documents must be legible and within their validity period. • All certificates or reports submitted shall be signed-off and dated by the person issuing the document. • For re-registration, no changes to existing information unless approved by MDA via a change notification.	√	
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) and a synopsis of the content of the CSDT; 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. The IFU is also known as the products 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.	√	
EPSP	• The Essential Principles (EP) checklist to the Malaysian EP as stipulated in the MDR 2012 and Guidance Documents on the Essential Principles of Safety and Performance of Medical Devices (MDA/GD/0007) shall be submitted. Alternatively, the checklist of EU or Australian Essential Requirements addressing similar elements as Malaysian EP can be submitted. • An EP checklist established for the medical devices includes information about the method(s) used to demonstrate conformity with each EP that applies, references for the method adopted and identification of the controlled document with evidence of conformity with each method used. • For the controlled documents indicated which are required for inclusion in the submission: a cross-reference of the location of such evidence within the submission.	√	

MEDICAL DEVICE REGISTRATION FORM	EXPLANATION/REQUIREMENTS	NEW	RE-REG
	• If any EP indicated in the checklist does not apply to the device: a documented rationale of the non-application of each EP that does not apply. • Methods used to demonstrate conformity may include one or more of the following: a. conformity with recognised or other standards; b. conformity with a commonly accepted industry test method(s); c. conformity with an in-house test method(s); d. the evaluation of preclinical and clinical evidence; e. comparison to a similar device already available on the market. • If outdated standards were applied, a gap assessment needs to be provided to demonstrate state of the art.		
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 recertification, no changes to existing information unless approved by MDA via a change notification application.	√	
Summary of design verification and validation documents	• This section should summarize or reference or contain design verification and design validation data to the extent appropriate to the complexity and risk class of the device. Such documentation should typically include: a. declarations/certificates of conformity to the "recognised" standards listed as applied by the manufacturer; and/or b. summaries or reports of tests and evaluations based on other standards, manufacturer methods and tests, or alternative ways of demonstrating compliance.	√	
Pre-clinical studies	• The preclinical studies are based on the device's intended use. – For general medical devices, it shall contain the results and critical analyses of all verifications and validation tests and/or studies undertaken to demonstrate the conformity of the device with the requirements of MDR 2012 and the applicable EPSP. It shall include a. biocompatibility tests conducted on materials used in a medical device; b. preclinical physical tests conducted on the medical device; c. preclinical animal studies to support the probability of effectiveness in humans d. software verification and validation – For IVD medical devices, it shall contain information on study design, complete test or study protocols, methods of data analysis, data summaries and study conclusions. The most common characteristics that must be validated should include but are not limited to- analytical sensitivity; limit of detection/ limit of blank/ limit of quantitation, analytical specificity; cross reactivity, interference; endogenous, exogenous, linearity/ assay's measuring (reportable) range, accuracy, trueness, shelf life/ projected useful life, precision (repeatability / reproducibility), traceability and expected values, cut-off value, stability of reagent, specimen stability, carryover, software verification and validation studies, usability testing (for self-test use), electrical safety testing report, another applicable test.	√	

MEDICAL DEVICE REGISTRATION FORM	EXPLANATION/REQUIREMENTS	NEW	RE-REG
Clinical evidence for medical devices	• An updated clinical evaluation report (CER) reviewed and signed by an expert in the relevant field contains an objective critical evaluation of all of the clinical data submitted about the device. Clinical evidence for general medical device may include: – A systematic review of the existing bibliography including the search strategy with sufficient detail. This should incorporate: a documented search protocol to a level of detail that allows the search to be reproduced, a selection strategy (inclusion/exclusion criteria), criteria for appraising the data (both favourable and unfavourable) to determine the contribution of each data set to support the conclusions, results of the literature search; and documentation of the appraisal to the extent that it can be critically reviewed by others; – Clinical experience with the same or similar devices which compares the clinical, technical and biological characteristics including identifying and justifying the related clinical impact for each difference; – Clinical investigation data including all pivotal clinical study reports; – Where applicable, other clinical experience data/real-world data (including device registries, post-market studies conducted in other jurisdictions) or post-market clinical follow-up (PMCF) including post-market data from all regulatory jurisdictions where the device (or a predicate or similar marketed device) has been marketed. • The clinical evaluation report shall be actively updated when the manufacturer receives new information from PMS that has the potential to change the current evaluation; if no such information is received, then at least annually if the device carries significant risks or is not yet well established or every 2 to 5 years if the device is not expected to carry significant risks and is well established, a justification should be provided. • In the absence of a CER, another CER with substantially equivalent information shall be submitted. A device is considered "substantially equivalent" if the following criteria are met: – Has the same intended use as the predicate device; and – Has the same technological characteristics as the predicate; OR – Has the same intended use as the predicate; and – Has different technological characteristics and does not raise different questions of safety and effectiveness; and – The device is demonstrated to be as safe and effective as the legally marketed device.	√	√ updated CER
Clinical performance for in-vitro medical devices	• Performance evaluation for IVD medical devices shall include the following: – The document should list the evidence presented, its characteristics (e.g. well-controlled studies, partially controlled studies, studies and objective trials without matched controls, well-documented case histories conducted by qualified experts, literature review, post-market data from another jurisdiction or a marketed device)) and provide a discussion of how this is considered sufficient to support the request for marketing for the requested indications. A tabular listing of clinical studies may be included in this section; – If any of the study IVD medical devices differ from the IVD medical devices to be marketed, including competitors' IVD medical devices, a description of these differences and their impact on the validity of the evidence in terms of support for the application for any device referenced in the application. This may include a detailed comparison of the clinical.	√	√ updated CPR

MEDICAL DEVICE REGISTRATION FORM	EXPLANATION/REQUIREMENTS	NEW	RE-REG
	– Guidance on clinical performance studies is also available in ISO 20916 In vitro diagnostic medical devices — Clinical performance studies using specimens from human subjects — Good study practice; – A discussion of the clinical evidence considered for the IVD medical device and support for their selection (i.e. what type of evidence was considered and why they were or were not used); – Discussion to support why the evidence presented is sufficient to support the application. – NOTE: Human factors testing that includes patients should be included here. • In the absence of a CPR, another CPR with substantially equivalent information shall be submitted. A device is considered "substantially equivalent" if the following criteria are met: – Has the same intended use as the predicate device; and – Has the same technological characteristics as the predicate; OR – Has the same intended use as the predicate; and – Has different technological characteristics and does not raise different questions of safety and effectiveness; and • The device is demonstrated to be as safe and effective as the legally marketed device.		
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. • This shall include brochure/product catalogue - 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, and etc. • For re-registration, no changes to existing information unless approved by MDA via a change notification.	√	√ updated label
Risk analysis	• Results of the risk analysis process conducted in accordance with ISO 14971:2019. This should include: – the latest risk management report; – a list of possible hazards of these devices; – the technique used to analyse risk; – the evaluation of these risks against the claimed benefits of the device; – the description on the method (s) used to control or reduce risk to acceptable levels; – the identification of an individual or organisation that carries out the risk analysis.	√	√ updated risk analysis

MEDICAL DEVICE REGISTRATION FORM	EXPLANATION/REQUIREMENTS	NEW	RE-REG
Manufacturer information	• The 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. 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, and storage of the device. • For re-registration, no changes to existing information unless approved by MDA via a change notification.	√	
Use of existing bibliography	• If clinical evaluation is done by conducting a systematic review of the existing bibliography, copies of all literature studies, or existing bibliography, that the manufacturer is using to support safety and effectiveness are required.	√	
Misc	• 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.	√	
SECTION 5: 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 conformity assessment body (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. • 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. • For re-registration, the QMS shall be updated.	√	√ updated QMS
List of manufacturing site – Manufacturing site's name, 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	
SECTION 6: PRE-MARKET CLEARANCE / PRE-MARKET APPROVAL			
Therapeutic Goods Administration (TGA), Australia	• The pre-market approval type is as listed in the MDA Circular Letter No.2/2014. • A declaration of conformity by the manufacturer shall be submitted, in addition to the TGA license.	√	√ If applicable
Ministry of Health, Labour and Welfare (MHLW) Japan	• The pre-market approval type is as listed in the MDA Circular Letter No.2/2014. • The certificate shall be translated into English language.		

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Health Canada	• The pre-market approval type is as listed in the MDA Circular Letter No.2/2014.		
Medicines & Healthcare Products Regulatory Agency (MHRA), United Kingdom	• The pre-market approval type is as listed in the MDA Circular Letter No.2/2014.		
Food and Drug Administration (FDA), USA	• The pre-market approval type is as listed in the MDA Circular Letter No.2/2014.		
European Union (EU)	• The pre-market approval type is as listed in the MDA Circular Letter No.2/2014. • A declaration of conformity by the manufacturer shall be submitted, in addition to the EC certificate issued by the notified bodies.		
SECTION 7: CONFORMITY ASSESSMENT			
Name of CAB	• A registered CAB name under Act 737	√	√ updated CAB report and certificate
CAB registration no.	• Registered CAB registration number		
CA certificate: valid from	• State CAB certificate validity date		
CA certificate: valid to	• State CAB certificate validity date		
CAB certificate and CAB report	• Certificate and report issued by a registered conformity assessment body (CAB)		
SECTION 8: 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.	√	√ updated PMS

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SECTION 9: DECLARATION OF CONFORMITY			
Declaration of Conformity	• The manufacturer shall be required to attest that its medical device complies fully with all essential principles for safety and performance and shall draw up a declaration of conformity in the format as specified in Appendix 3 of the Third Schedule of MDR 2012 and Guidance Document on Declaration of Conformity (MDA/GD/0025). • The updated DoC shall be prepared with the manufacturer's letterhead and signed by the company's top management. The QMS information shall be valid and vertical and horizontal standards shall be stated. • For reregistration, an updated DoC shall be provided. • 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.	√	√ updated DoC

-End of Table -