FAQ

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NO.	CONTENTS
1.	Q: What is the procedure for medical device registration? A: Application for medical device registration shall be done on-line. The system for on-line registration is called Medical Device Centralized Online Application System (MeDC@St) which can be accessed via this link: http://www.mdb.gov.my/medcast/login/. More guidelines on how to make an on-line application can be accessed in MeDC@St page.
2.	Q: Can we use the same ID and password of MeDVER to register in MeDC@St? A: Yes, if you choose to use the same ID and password, but you still need to re-register in MeDC@St.
3.	Q: Does the information captured in MeDVER will be transferred to MeDC@St? A: No, a new application shall be made via MeDC@St for product registration and establishment licensing.
4.	Q: How can we follow up with the previous products registered in MeDVER? A: MeDVeR has already ceased to operate and no information that has been entered in MeDVeR will be used.
5.	Q: I had unintentionally entered wrong email address when I create a MeDC@St account what should I do? A: Please email your problem your together with your MeDC@St account details; i.e Business Registration number and the correct email address to medcast@mdb.gov.my. Our IT team will assist you.

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6.	Q: My company is carrying a few different brands of medical devices. How can I list them all? A: You can download the template in Excel format that is provided in MeDC@St to list your medical devices and upload back the list at the appropriate column in MeDC@St.
7.	Q: If the person responsible and contact person for the establishment is the same, should I enter twice? Is the Letter of Authorization to authorize the contact person required? A: In MeDC@St page, fill up the responsible person section. At the contact person section, tick at the box "same as responsible person of the establishment". All the information from responsible person of the establishment will automatically be filled in the contact person section. Letter of authorization to authorize the contact person is not required if responsible person is the same as contact person.
8.	Q: I have created MeDC@St account. Do I need to apply for establishment licence, medical device registration or both? A: All establishments, ie manufacturer, authorised representative (AR), importer and distributor must apply for establishment licence. However, only manufacturer and AR need to apply for medical device registration.
9.	Q. Can I pay the fee online? A: For now only bank draft is accepted. We will make appropriate announcement when the online fee payment is ready.

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10.	Q: Where can I find submission ID number to write on the back of bank draft A: You can find the Submission ID number at your Payment Advice Slip and the number must be written at the back of the bank draft when you make the payment.
11.	Q: Whose ID number should I write at the back of the bank draft? A: The contact person ID (ie the IC or passport number) that is provided during the application of establishment licence.
12.	Q: What is a medical device? A: The term “medical device” covers any product used in healthcare for the diagnosis, prevention, monitoring or treatment of illness or handicap but excludes drugs. Please refer to Section 2 of Medical Device Act 2012 (Act 737) for complete definition of term “medical device”.

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13.	Q: What are the requirements for medical device registration? A: Medical device registration shall be made by the manufacturer of the medical device or the authorized representative (AR) in the case of medical devices that are manufactured in foreign country. To register a medical device, the manufacturer or AR shall: (i) determine the class of the medical device according to First Schedule of Medical Device Regulations 2012 (MDR2012); (ii) determine grouping for the medical device according to second Schedule of MDR2012; (iii) conduct conformity assessment to demonstrate conformity of the medical device to the requirements in Third Schedule of MDR2012; (iv) collect evidence of conformity of the medical device to all requirements; (v) depending on the class of the medical device, appoint a conformity assessment body to conduct assessment on the conformity; (vi) prepare Common Submission Dossier Template (CSDT) including its supporting documents for medical device registration submission; (vii) prepare the Declaration of Conformity (DoC); (viii) pay application and registration fees accordingly; (ix) make application submission via MeDC@St. You are advised to refer to Sections 5 and 6 of Act 737 and Part III of MDR2012 for more detailed requirements.

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14.	Q: How to classify a medical device? A: Medical device classification excluding in-vitro diagnostic (IVD) medical device shall be done according to 16 rules as prescribed in Appendix 1 of First Schedule of MDR 2012, whilst classification for IVD medical device shall be done according to 7 rules as prescribed in Appendix 2 of First Schedule of MDR 2012. Please refer to the Schedule for the complete rules for medical device classification.
15.	Q: Who is responsible for the classification of medical device? A: Section 3 of Act 737 provides that classification of a medical device shall be done by the establishment in accordance with the prescribed manner and in the event of any dispute between an establishment and a conformity assessment body over a classification of a medical device, the matter shall be referred to the Authority, for its decision.
16.	Q: How to group a medical device? A: Medical devices may be grouped into any one of the 6 groups namely single, family, system, set, in-vitro test kit or in-vitro cluster. Three basic rules shall be applied to group medical devices, namely: (i) one generic proprietary name; (ii) one manufacturer; (iii) one common intended purpose. All rules shall be fulfilled when applying the grouping rules and detailed rules of medical device grouping are prescribed in Second Schedule of MDR2012. Please refer to the Schedule for the complete rules for medical devices grouping.

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17.	Q: What is the fee for product registration? A: Fee for medical device registration is based on the class of the medical device; the higher the class, the higher the fee to be paid. Please refer to Fifth Schedule of the MDR2012 to get the details of fees payable for registration of medical device.
18.	Q: How long is the transition period for establishment licensing and product registration? A: Section 80 of Act 737 provides a one-year and 2-year transition period for establishment licensing and medical device registration respectively from the effective date of Act 737 i.e. 1st July 2013.
19.	Q: How can I know the medical device is safe and registered under MDA? A: Registered medical devices are considered safe as they had undergone and demonstrated conformity to essential principles safety and performance of medical device. They will be listed in MDA website.
20.	Q: Is a contact lens a medical device? A: Contact lens that is used to correct refractive vision conditions (e.g., myopia, hyperopia, astigmatism, presbyopia) is a medical device. Therefore, such contact lens is subject to the regulatory requirements specified in Act 737. However, cosmetic lens without corrective features is not a medical device.
21.	Q: Where is the reference for the Essential Principles and Safety Performance in MDR2012? A: The reference for Essential Principles and Safety Performance can be found in Appendix 1 of Third Schedule of MDR2012.

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22.	Q: What documents of QMS shall be submitted for medical device registration? A: ISO 13485 certificate issued by registered CAB shall be submitted for registration of medical devices. For further information on the requirement of QMS for medical device registration, please refer to Third Schedule of MDR2012.
23.	Q: Does a standard Declaration of Conformity (DoC) format is available from MDA? A: DoC format is provided in Appendix 3 of Third Schedule of MDR2012.
24.	Q: What are the documents required for registration of Class A and B of medical device? A: MeDC@St prescribed the forms and the documents to be submitted for registration of medical devices. Besides filling in the required information: (i) for a Class A medical device, the document to be submitted is the declaration of conformity; (ii) for Class A sterile medical device or medical device with measuring function, the validation report for sterility or measuring function shall also be submitted; (iii) for Class B medical device, the documents to be submitted are CSDT and its supporting documents, device description, summary of design verification and validation, sample of label, instruction for use, result of risk analysis, manufacturing process, declaration of conformity; (iv) attestation for medical device registration application shall also be submitted for both Class A and Class B medical devices.
25.	Q: What are the labeling requirements for medical devices? A: The labeling requirements are provided in Sixth Schedule of MDR2012.

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26.	Q: How to market a medical device that is manufactured in other countries? A: For an imported medical device, the foreign manufacturer must appoint/authorize an authorized representative (AR) in Malaysia and the AR shall obtain for an establishment license. The AR shall: (i) obtain establishment licence under Act 737 to operate as AR; (ii) represent the foreign manufacturer with regard to manufacturer's obligations under Act 737; (iii) maintain good linkage with its foreign manufacturer and should be able to obtain the support of its foreign manufacturer when required; (iv) be a person domiciled or resident in Malaysia or a firm/company constituted under the laws of Malaysia; (v) apply for medical device registration and may import and distribute the medical device itself or authorize importer/distributor to import/distribute the medical devices on its behalf.
27.	Q: What is an importer? A: An importer is a person or company appointed by an AR to import medical devices registered by the AR from foreign country into Malaysia. An importer shall only import registered medical devices authorized and on behalf of the AR. An importer shall obtain an establishment licence to conduct its activity.

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28.	Q: What is a distributor? A: A distributor is a person or company appointed by an AR (for medical device manufactured in foreign country) or a manufacturer (for locally manufactured medical device) to further medical devices registered by the AR or the manufacturer into the Malaysian market. A distributor shall only distribute registered medical devices authorized and on behalf of the AR or the manufacturer. A distributor shall obtain an establishment license to conduct its activity.
29.	Q: Is there any issue if AR uses different name with the manufacturer? Can we be the brand owner of the medical device? A: There is no issue if the name of the distributor differs with the name of the manufacturer. However, an AR cannot be the brand owner.
30.	Q. Does a trading company need to apply a license or not before we can sell our own brand to retailer market? A: Act 737 regulates all parties who are involved in conducting activities that may affect safety and performance of a medical device throughout its life cycle. Such activities include design, manufacture, transportation, importation, storage, tracking, usage, maintenance, etc. From your question it seems that you own the brand of the medical device that you are dealing with and according to Section 2 of Act 737 a brand owner is a manufacturer. A manufacturer shall possess a valid establishment license under Act 737.
31.	Q: What are the applicable regulatory requirements for a packaging company that is not involved in medical devices manufacturing? A: A manufacturer shall be fully responsible to comply with all the regulatory requirements relating to the manufacturing of medical device including its packaging. The requirements for packaging shall be assessed as part of conformity assessment of the whole manufacturing process of the medical device.

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32.	Q: What is Good Distribution Practice Medical Devices (GDPMD)? A: Various people or entities who are responsible for procurement, transportation, delivery, storage, device tracking, installation, commissioning, service, maintenance and calibration, need to be appropriately managed and regulated to ensure safety and performance of medical devices at the point of use. The level of risks associated with these activities may be of similar degree as those in the manufacturing environment and the lack of control over these activities may affect safety and performance of the devices. GDPMD specifies the requirements for a quality management system (QMS) to be established, implemented and maintained by an establishment in carrying out activities in medical device supply-chain to comply with medical device regulatory requirements as stipulated in Act 737 and its subsidiary legislations. GDPMD requires an establishment to demonstrate its ability to maintain quality, safety and performance of medical devices in compliance with the regulatory requirements throughout the supply-chain. The requirement for GDPMD is stipulated as the QMS requirement for those involved in medical device supply chain, namely the AR, importer and distributor as required para 11 of Third Schedule of MDR2012.
33.	Q: When will GDPMD be implemented for medical device companies in Malaysia? A: The implementation of GDPMD has started officially on 1 July 2013 in Malaysia.
34.	Q: For distributor, what are the differences between the GDPMD and licensing of distributor? Does all the GDPMD need to be reviewed by the CAB or RA? A: GDPMD is a requirement for establishment licensing of distributor. It is a type of QMS to ensure the safety and performance throughout the medical device supply chain. The GDPMD will be assessed and certified by the CAB. The certificate issued by the CAB shall be submitted as part of the requirements for establishment license application.

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35.	Q: Is all the information about manufacturers, distributors and importers confidential? A: Only certain non-confidential information on licensed establishments and registered medical devices will be made available for public access. Sections 67, 68 and 69 of Act 737 and Regulations 21 and 22 of MDR2012 give the provisions on how the Authority shall handle the information.
36.	Q: What are the requirements for CAB registration? A: The requirements for registration of CAB are provided in Sections 10 and 11 Act 737 and Regulations 8, 9 and 10 of MDR2012. Detailed requirements for registration of CAB are as stipulated in Fourth Schedule of MDR2012 which include: (i) requirements on organization; (ii) requirements on resources and technical competency; (iii) requirements on independence and impartiality; (iv) requirements on quality management system.
37.	Q: Please provide list of certification bodies approved by MOH so that we can begin preparation for our branch in Malaysia. A: The list of CAB is available on our website. Besides the list of CAB, you will also find other useful information.
38.	Q: Is CSDT required for registration of all medical devices? A: CSDT is not required for Class A medical device.

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39.	Q: How do I report an adverse event? A: An adverse event report regarding medical device can be made via our website http://www.mdb.gov.my under <Post Market Activities> <Adverse Incidents Reporting> <Report An Incident> Choose appropriate form for example AER Form 1 for Manufacturer, Distributor and Authorized Representative and AER Form 2 for Medical Device User.
40.	Q: Does the overview of reportable adverse events and Field Corrective Action (FCA) need to be worldwide or just the ones from Malaysia? A: The requirement of reporting an adverse event, please refer to Section 40 of Act 737. However, there is no requirement to report FCA under Act 737.
41.	Q: Where can I get the information regarding trainings or seminars organized by MDA? A: All events will be announced on MDA website. Please visit the website regularly to get the latest updates.

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