FAQ

GENERAL

Question 1

Can Establishment apply for Export Permit during transition period?

Answer

Refer Sect 45 (1), all medical device must be registered to apply for export permit

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Question 2

During transition period, can establishment continue to import, export and placed medical device in market?

Answer

Refer medical device (exemption) order 2015, P.U (A) 135/2015, establishment must submit an application for registration before continue import, export and placed medical device in market

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Question 3

During transition period, can establishment use acknowledgment letter to apply for export permit?

Answer

No. Export permit is issued once the product is registered and establishment is licensed.

Question 4

During transition period, can establishment advertise the medical device?

Answer

No. Refer Section 44 (1) all medical devices must be registered to advertise

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Question 5

What document need to be reviewed by CAB for the purpose of registration of a medical device?

Answer

Refer to medical device regulation 2012, third schedule;

- **a)** Conformity assessment of quality management system
- **b)** Conformity assessment of post-market surveillance system
- **c)** Conformity assessment of technical documentation
- **d)** Declaration of conformity

For medical devices approved by recognise country is based on Circular Letter No. 2 Year 2014.

Question 6

When is the dateline to resubmit the document during evaluation of medical device registration?

Answer

90 days. Refer to Part III of Medical Device Regulation 2012.

Question 7

Can classification of medical device in other countries be accepted in Malaysia

Answer

Classification of medical device in Malaysia will be based on First Schedule of Medical Device Regulation 2012.

Class A

Question 1

What is a Class A low risk medical device?

Answer

All Class A medical devices which are non-active, non-sterile and have no measuring function are considered to be low risk medical device.

Question 2

What is the requirement to obtain permission to import and place Class A low risk medical device in the Malaysian market?

Answer

Referring to the Circular Letter No. 3 Year 2014 (Exemption of Medical Device from registration), all Class A low risk medical device are exempted from registration requirements.

However, MDA shall be given notification and the establishment must first obtain a letter of notification as permission prior to import and placing any Class A low risk device on the Malaysia Market.

Question 3

Who can apply for this Class A low risk notification?

Answer

Class A low risk medical device notification shall be made by the manufacturer of the medical device or the authorized representative (AR) in the case of medical device that are manufactured in foreign country.

Question 4

How long does the evaluation take?

Answer

It will take approximately 60 working days in issuance of response to the application.

LICENSE

Question 1

Does tendering agent need to have establishment license?

Answer

No, as long as they do not involve in any activities related to distribution. Tendering agent are strictly for the purpose of procurement with the government hospital.

Question 2

For tendering purpose, the hospital put in requirement that it is a must to attached MDA certificate, or the tender will be rejected.

Answer

You may asked for the copy of establishment licensing certificate directly from your manufacturer/ Authorized representative (AR) / distributor. It is a requirement for Ministry of Health procurement division to ascertain that this products are from a licensed establishment and registered. MDA will not provide any letter for tendering agent. If they are still facing a problem, the tendering agent may call directly to MDA.

Question 3

If manufacturer want to change AR, what if current AR do not want to notify?

Answer

In this case, establishment must solve their business issue as in their contract and AR will be appoint as per agreement with letter of authorization from the manufacturer. The new AR is responsible on the new product.

Question 4

If we submit the audit report (ISO 13485) from SGS (UK) our Notified Body, why this is not accepted by MDA?

Answer

Requirement for CAB recognition must be from a local CAB in Malaysia that are registered under Section 10, Act 737.

Question 5

How long does it take to get the establishment license after application and submission?

Answer

After completion of all documents, 1 month timeline for establishment license since 1st January 2015.

Question 6

Currently have applied license as AR and already approved; But we need to create new account as manufacturer as we are importing some devices under our own brand. We couldn't reopen new account under MedCast. Please advise how to reopen/proceed with establishment licensing and product registration.

Answer

Please write an official letter to MDA. MDA will re-open your application. Please be noted that transition period for establishment licensing has ended. Application after 1st July 2014 will not get benefit of transition period of

licensing. In the meantime, establishment is advice to apply for ISO 13485. After complete documentation, licensing certificate will be given.

Question 7

Now we contract out our product manufacturing. With our brand, we already in the process of getting GDPMD. Do we need ISO 13485?

Answer

For manufacturer, it is required to have ISO 13485, not GDPMD.

Question 8

We applied/register MDA under enterprise, but upgraded to Sdn. Bhd.

Answer

Please write an official letter to MDA to notify us on this

Question 9

Do manufactures need a local AR for class A exempt devices or if they can sell directly?

Answer

Yes, it is still required under Act 737 to appoint local AR

Question 10

What are conditions set by MDA for provisional GDPMD certificate issued by CAB?

Answer

Establishment can apply establishment license once they get provisional certificates. Establishment need to update MDA once they get full certificates.

Question 11

As appointed representative, our distributor is not registered, can we be penalized for supplying our product to them?

Answer

If the distributor is not licensed, then, as AR, you are responsible to not appoint the establishment as your distributor.

Question 12

Does the authorized representative (AR) require local staff working in the Malaysia office? If our Singapore office staff is handling everything in Singapore, is this acceptable?

Answer

If the medical device is place in Malaysia market, then it is subjected to Act in Malaysia. AR must have licensed and domicile in Malaysia.

Question 13

If the legal manufacturer engage 2 manufacturing sites, how should we register product?

Answer
MDA will refer to legal manufacturer only.

Question 14
Is online sales regulated? What will be done to online sellers sell products that are not registered?

Answer
MDA will take action to the individual involve, not only the establishment under Malaysian act.

Question 15
Can I register the Medical Device if my company GDPMD certified scope is not covered the Medical Device category? For example GDPMD covered only dental device but can I register implantable device?

Answer
No, you have to get the scope for implantable first

Question 16
How do MDA trace on multiple AR?

Answer
One product is registered by only 1 AR, when another AR try to register the same product in the system, the system will be traced that there is another AR bringing the same device. MDA will trace when this is detected.

Question 17
What are the document require for importation by custom starting from 1st July 2015?

Answer
Customs will inquire on the establishment license and product registration. Product registration still under transition period until 30 July 2016.

Question 18
How long or is there a period for establishment license progress?

Answer
Process output for establishment license for 2015 KPI – 30 working days with complete application

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Question 19
Previously we are the distributors and importer for foreign manufacturer for class A Medical Device. However the foreign manufacturer had been bought over by other company oversea and the new company didn't continue to supply the Medical Device to Malaysia. Can we do placement the available stock to Malaysia market?

Answer
Yes, you still can do the placement in Malaysia market and the medical device are responsible by the Authorised Representative

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Question 20
Is the acceptable for MeDCASt system if the EL and MD register done parallel, example establishment license pending cert because awaiting CAB audit schedule. Is the company allowed to place the product in the market?

Answer

Answer Depend on when you submitted your application. It is allowable for you to do parallel application, but whether you can continues your business is depend on submission date of your application. For establishment license submitted before 30th June 2016, you may continue business; if submitted medical device registration before 30th June 2015, the medical device may be allowed to place in the market.

Question 21

Do we need to apply many license as Authorised Representative (AR) of we brings products from different foreign manufacturer?

Answer

One (1) AR license can be used to represent many different manufacturer and many products; However, only one (1) product must be represent by one (1) AR.

Question 22

How do we notify MDA in terms of changes (E.g. change manufacturing site from one country to another country etc.)?

Answer

Have to write to MDA and application will be open for changes. In future we will come out with system that will allow changes notification can be done anytime. Currently, write to us and MDA will facilitate for additional necessary changes. If changes of certificate, the latest certificate must be submitted to MDA. E.g. changes of manufacturing sites for GDPMD/ISO 13485, certificate must be submitted to MDA together with the application for amendment.

Question 23

Where can we check list of company that has already obtained establishment licence and GDPMD status?

Answer

The system is still on-going process of upgrading. So, it will be listed on the website once the system is ready.

Question 24

I need more explanation on contract manufacturer because as mention the contract manufacture no need to apply license what criteria describe contract manufacture?

Answer

Contract manufacturer only doing manufacturing for other brand owner but didn't own the brand. Criteria for manufacturer: Brand owner; and Do manufacturing activities themselves or outsource to OEM

Question 25

We are the AR for company A that would like to register x-ray machine. Is there any additional requirement that we need to comply in order to register with MDA? Do we need to register under AELB or MDA?

Answer

AELB licensed for Act 304 and for MDA, Act 737. For radiation apparatus such as x-ray, it is consider as medical device. Thus, the company need to have a licensed and registered the medical device under MDA.

Question 26

For a company with 3 plants in 3 separate locations / addresses are all 3 needs to have establishment licence?

Answer

It can be treated as one and it can be combine in the certification of ISO 13485- during certification process CAB have to access all the plants and covered under 1 certificate

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Question 27

Is MDA is going to have a process to manage samples to ensure safety of establishment analysing used samples from complaints

Answer

According to Section 6, Act 737- samples may be required. If it is inquired by MDA, then you must send the sample. If not, there's not necessary to send the sample.

Question 28

For establishment already in industry for more than 20 years with ISO 13485 by CAB not in list of MDA, but well established in the world, why does the establishment need to re-certificate?

Answer

Refer to Act 737; Assessment procedure must be carried out by a registered CAB.

Question 29

What are the legal procedure that need to be done as a distributor?

Answer

Need to have the establishment license. To comply with the requirement you have to get the GDPMD certificate. As a distributor, you need a letter of authorization from the AR or Manufacturer. U also have to keep the distribution record and you will be the first point of complaint and after that you have to pass it to the AR. AR can have many distributor around Malaysia. As a distributor no need to apply product registration. MDA will know what types of product that distributor sell under AR.

Question 30

Who need to be certified on Good Distribution Practice for Medical Device (GDPMD)?

Answer

AR, distributor and importer must be certified on GDPMD

Question 31

Definition of retailer and distributor?

Answer

The different between retailer and distributor, the AR must appoint you as the distributor whereas for retailer like a pharmacy outlet didn't need the authorization from AR. Distributor need authorization letter and have a lot of stock. The concept we have in our law is the manufacture can appoint distributor. Whoever appointed, it is a distributor and after distributor is no more. Once distributor distribute to other company that is not distributor. In the act, only manufacturer and AR

Question 32

If we do not hold any brand, but just a reseller, what are we categorised as?

Answer

A part of distributor responsibilities, it must make sure that reseller/retailer is operating with the requirement of the law. For example, they can ask you to certify for GDPMD but not a purpose of obtaining the licence. Distributor must make sure that product safe until it reach to consumer. If anything wrong to the product, the distributor will take the responsibilities. If distributor cannot control the reseller, then the reseller can obtain GDPMD because they will be audited and to ensure the product in a good condition.

Question 33

How about we sell to central medical store?

Answer

The product already sold to the user, so the user keeps their stock in the central store; there are not distributor responsibilities anymore. The second level and third level are not covered by the Law.

Question 34

When a product comes in to Malaysia, how MDA determine the product from an authorized AR? For example, somebody else import the same brand. How MDA control?

Answer

Definitely one brand for one AR, in future the system will able to know it and alert MDA. At these moment, custom department will know, you have to show a letter to prove that you an AR. We will give a licence and list of products. If you cannot show a letter, custom will hold your goods. If somebody else break the law, they declare that goods not a medical device, you should inform us, then our enforcement will come.

Question 35

New product from new manufacturer, then they want to make us their new AR importer, do we need to apply the whole things?

Answer

You need to tell us if affect your GDPMD certificate or not, for example previously you are distributing condom, catheter and glove. Suddenly IVD reagent, the requirement for IVD reagent storage and glove will be different so you need to tell us the new GDPMD cover the new product. You have to get confirmation from CAB. CAB will give you report and you need to submit a letter to MDA. Then we will put it in the system your new role.

FINANCE

Question 1

Can we combine the bank draft when make application fees payment to MDA? For example combined 20 payments of application fees for Class B and Class C application under the same bank draft

Answer

The PAYMENT ADVICE must be printed and attached together with bank drafts to indicate the details of payment.

Payment for application fees and registration fees of different class of medical devices CANNOT be combined in one bank draft. It is advisable to split the payment in different bank drafts.

The fees of maximum of 5 different application submissions can be combined together in a bank draft.

Post Market, Surveillance and Vigilance

Question 1

Will MDA start investigation and take legal action against the distributors who distribute/sell counterfeit products?

Answer

Counterfeit product is not under Act 737 – for counterfeit, it is under KPDNKK and they do enforce Akta Perihal Dagangan 2011 which cover counterfeit product includes medical devices. Report can be made directly to Bahagian Penguatkuasaan KPDNKK and copy should be provided for MDA for notification purpose.

Question 2

Code of advertisement, when are we participating it to be published?

Answer

We are finalising the document and put it on website for the public comment. Comments received will be discussed in committee for discussion and consideration.

Question 3

We regards to post market surveillance, if there is an issue with the device that does not affect safety to a patient e.g. cannot switch on or off, is it reportable?

Answer

If it doesn't affect safety and performance; do not need to report (e.g.: switches break, contact point lose). As an example if a series of the investigation by the manufacturer reveals that; the switch ON and OFF mechanism that fail will trigger electrocution or will affect the device operation's performance, then the answer is YES ,need to report

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GENERAL MEDICAL DEVICES REGISTRATION AND IVD

Question 1

What shall be the easiest process

Answer

The process that have been finalised by MDA is complete and simple.

Question 2

Is the fast track medical device regulation guidance documents and circular in the website still valid applicable to current situation in view of transition period? If no, why?

Answer

As outline according to Section 80 Act 737, A person who, prior to the appointed date, has been apply for the registration of the medical devices under section 6 may continue their business activity.

Application of registration in MeDC@St:
For Class A (sterile/active/ and or with measuring function), need to submit 'declaration of conformity' (DoC) where the establishment must have a quality management system (QMS) in place. After MDA have review the application, an acknowledgment letter will be given through MeDC@St stating that the establishment that they may continue business activity as per usual.

For Class B, C and D, 4 complete documentation is required for evaluation:
(1) Conformity assessment report from CAB
(2) 'Post-market clearance'
(3) 'Technical File', and
(4) 'declaration of conformity (DOC)'.

If the documentation is not complete, the application will be return to establishment to return complete application within 90 days. If there are problems to register with CAB, establishment must submit formal letter to apply to MDA for extension of registration period provided with evidence and supporting documents. For local manufacturer, shall undergo full conformity assessment by registered CAB.

Question 3

If a contract manufacturer is the product owner of accessories that can be use with the primary product of the applying manufacturer for product registration;

1. How will the product registration be done?
2. Who should notify MDA when there are changes in the accessories?

Answer

Accessories is also a medical device (refer to Guidance document on classification of medical device). Since the contract manufacturer is the brand owner of the accessories, they are considered as manufacturer and must have establishment license as manufacturer and shall apply for medical device registration

1. For registration procedure, please refer to guidance document of how to apply for medical device registration (download at MDA website)

2. Manufacturer must notify MDA when there are changes in the accessories.

Question 4

Timeline for corresponding to request of additional info during registration?

Answer

90 days for medical device registration.

Question 5

Possible to submit product registration of class B, C and D although certain documents not available (e.g CAB assessment)? Current system not allowed to do so.

Answer

Currently, the MeDC@St system is open for submission and the CAB assessment is not mandatory yet for submission until end of transition period.

Question 6

Conformity assessment procedures for Medical Device approved by recognise countries?

Answer

Verification after 1st July 2015, have to go through the normal route. If you have approval from 5 reference countries you can use the circular 2 to do the verification otherwise you will need to full verification if you do not have approval from 5 reference countries.

Question 7

Impact of not registering

Answer

Section 5 (2) Act 737: The person will be liable to a fine not exceeding two hundred thousand ringgit or to imprisonment for a term not exceeding three years or to both.

Question 8

Dateline

Answer

Until 30th June 2016 is transition for medical device registration. You may still apply after 1 July 2016, but will not get benefit of transition period.

Question 9

Cost of registration

Answer

Refer to Fifth Schedule Medical Device Regulations 2012

Question 10

What is the timeframe given to make the application fee payment after submission in MeDC@St ?

Answer
All fees shall be paid 30 days after notifications on the payment advice are notified in the MeDC@St Account. Applications will be dropped from the system if the payment is not received within the specified time.

Question 11
Is the registration application will only be considered once the application fee be submitted or once the registration submitted but the application fee yet to be submitted by the applicant?

Answer
The medical device application will only be considered after the payment of fee.

Question 12
How to register a medical device that are imported into Malaysia where my company name is on the box, but we are not the manufacturer?

Answer
AR / manufacturer must register the medical device

Question 13
CSDT not required for Class A MD, however is it a mandatory field in MeDC@St ?

Answer
No, CSDT is not mandatory in MeDC@St for Class A

Question 14
'How to add product codes (SKVs) into a medical device system that already been submitted to MeDC@St? This happened as the source company just released a line extension.'

Answer
Please write an official letter to MDA for request of amendment to product codes. If the product is not yet registered, MDA will open the system and return application to you for amendment. If not, it will be done manually.

Question 15
How MDA can assure us that if the competitors can still sell without registering their products?

Answer
If there is information, please write a complaint and we will conduct an investigation to the non-registered medical device. However, MDA may detect this by auditing, also the medical device must be re-register every 5 years and together with details from procurement by hospitals / agencies. If these medical device are detected to be non-registered, enforcement will be taken. And if find guilty, MDA their establishment license may be revoke.

Question 16
If we can't get GDPMD certificate before 1st July 2015, can we register device after 1st July 2015?

Answer
Establishment is advised to register the medical device to get benefit of the transition period for registration of medical device.

Question 17
Medical device under the same class B but different GMDN (40548, 40549) can we apply under one application form?

Answer
If the medical device comply with 'grouping rule' that are allowed for the medical device, these medical device can be register under one application.

Question 18
Where to refer for medical device category?

Answer
You may refer to Medical Device Regulations 2012 or you can fine this on the MDA website.

Question 19
My product is registered before 30th of June 2015. I have paid the application fee. A change happens on July 2nd. What should I do as an AR?

Answer
If there is no major changes involve (e.g safety and performance), then it is not necessary.

Question 20
Registration Fee – can MDA offer some discount/promotional period during this transitional period to encourage more devices being submitted at once?

Answer
Scheduled fee are already stated in Medical Device Regulations 2012 and is not subjected to GST. Fees are the amount that needs to pay. No discount is given.

Question 21
Is circular letter no 2 still valid/active?

Answer
All of the circular are still valid until further notice.

Question 22
Since IVD products regulated under Medical Device Regulatory, do me still need Pharmacy License to import the product such as ELISA kits?

Answer
ELISA kit is IVD medical device, so you have to comply with Act 737

Question 23
How do we apply for changes in our CSDT which is already submitted MeDC@St?

Answer
Email or write to MDA prior to approval of changes and system will be open to allow changes. Upon request must be go through IT department

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Question 24
Under the "Document Applicable" stated "YES", "NO" & "N/A". The "NO" applicable same as "N/A" applicable. Which one should we choose? MeDC@St

Answer
If you have the document, you may just tick yes, if you don't have any you can tick No or N/A and you may justify it in the space

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Question 25
My CSDT consist of Device description, design verification, etc. Do I need to split the sections & submit under separate sections or I can submit as one go under CSDT sections?

Answer
GMD all section element under CSDT should upload whole CSDT in system and supporting document must be uploaded in the specific section for GMD. For IVD MD, you have to just click and declare and all the information consists in your CSDT and uploads it

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Question 26
Can "safety declaration" replace/meet post market history?

Answer
No, you can't use this safety declaration. You have to give report of all the post market history upload on the MeDC@St and declare

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Question 27
How details required for technical file to be review by CAB? Required selected product or all?

Answer
Details in technical file is dependent of your device class. Conformity Assessment on medical device shall be conducted in accordance with Medical Device Act , Medical device Regulation and Circular No. 2

Question 28
Product classified as Class A in Japan but as class B in Malaysia. The product does not have an approval from Japan, only notification, will if consider as "approval"?

Answer
Class B in Malaysia, need to prepare CSDT and submit. If you can prove, submit all documents for our verification prior to approval; if not, you will not be eligible.

Question 29
For grandfather devices that will be phased out in a year, supporting documents are insufficient and the manufactures will not generate data to support. Please advise how to write on the CSDT/ registration?

Answer
Submit all the document of the product. We will review first. If not sufficient, we will contact with you.

Question 30
For those Medical Device not register before 30th June 2015, can I still keep these device inside the warehouse after the date?

Answer
Yes, provided you do not place it in the market

Question 31
After 1st July, for new product registration, what is the license approval timeframe?

Answer
After complete documentation:

Class A - 30 days

Class B - 100 days

Class C - 180 days

Class D - 220 days

Question 32
Medical device registration that don't have 5 reference countries notified body and only manufactured locally and sold in local market only what document to be uploaded?

Answer
For medical device that has no approval, only Class A will be considered for evaluation; otherwise need to go through the normal route (full evaluation by CAB). You need to get conformity assessment for the medical device.

Question 33
If the medical device registration is done after the transition period is over, what are the steps to be taken for registration?

Answer
After the transition period, all the company are still allowed to register their products. This registration is subjected to the written circulars and Medical device Act 737. If you have registration from any 5 reference country you may proceed with the verification; if not must go through full assessment. After 30th June 2015, need for product registered / certify before place in the market. Product cannot be placed in the market until it is registered. Those submitted during transition period will be given benefits of the transition period and if fast track registration is approved, these will be additional benefit to the transition period.

Question 34
Are products that are previously registered under BPFK considered to have prior approval?

Answer

After Act 737, there are product that have been classify as medical device. Once the products that are registered under NPCB ends, then these product must be registered under MDA.

Question 35

Will combination device qualify for fast track registration? If no, how can MDA ensure that there is no disruption of supply of companies?

Answer

Combination product- see who is the custodian first. If mode of action under drug, e.g. insulin pen mode of action is insulin then it is pharmaceutical, you need to register to BPFK first.

Question 36

When will the guidance documents for combination device be published?

Answer

We are in the process of developing a guidance document for combination product together with NPCB.

Question 37

Different classification from different country

Answer

This will be treated case by case basis; If provided evidence and supporting document we will make consideration of the classification. If not, must follow the Medical Device Regulations 2012. MDA will also call for discussion if needed.

Question 38

For product that is a system (centrifuge machine), can we register it together with our kits as a system?

Answer

Centrifuge is medical device; If it is post as a system, then it is supply for the system alone; if you want to supply separately, must register single (refer medical device grouping)

Question 39

If we describe the expiry date of QMS on document, do we need to revise all documents at the update of QMS certificate?

Answer

Yes

Question 40

Documents and Conformity Assessment certificate from oversea manufacturer. Are those documents required to be certified true copy and who can qualified to certify it?

Answer

These documents are not required to be certified true copy, these Declaration of Conformity and Conformity Assessment to be certify by local CAB

Question 41

Can MDA accept DOC from the foreign manufacturer already have premarket approval?

Answer
DoC must be prepared according per our template in medical Device Regulations 2012. You may change the format, but not the content.

Question 42
Can one DOC include all products from same manufacturer but for different submission

Answer
Yes. However, you have to be specified details according to Class / grouping of the medical device in the DoC. Template for the DOC provided in the MeDC@st system

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Question 43
For products that falls into a FAMILY of SYSTEMS, how will the details of each SYSTEM be filled up in the application?

Answer
The applicant must details each particulars in the FAMILY / SSYTEM in the excel spreadsheet available on the MeDC@St. You have to download and fill the required details.

Question 44
What should be described in 6.4: summary of design verification and validation document?

Answer
Refer to 'Design and manufacturing requirements' in Medical Device Regulations 2012

Question 45
Letter of acknowledgment

Answer
After payment made, only then letter of acknowledgement will be given. It is auto-generated from the system and printable by the applicant

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Question 46
After getting registration certificate through fast track system, we also need to have conformity assessment by CAB within 5 years, then we submit the report and certificate issued by CAB to MDA. Do we need to pay registration fee again at that time?

Answer
Circular 7: When you fulfil and authority satisfy with all your documentation except for the conformity assessment in submission, you have to pay the application fee and once we notify you, you can pay registration fee for the first time within 5 years. After 5 years, you need to register your product again with the relevance conformity assessment certificate and report.

Question 47
What happens when these external devices break down and need to be sent back to manufacturer outside Malaysia? Will there be any issue with importation of the repaired device or any exemption for this situation?

Answer

Establishment must register the medical device since when the medical device are imported back into Malaysia, letter from MDA must state for exemption.

Question 48

Will there be a list of medical devices approval by MDA and available online for public information?

Answer

In future, the list of approved medical device will be available online for public information. Currently, we are still in the process registration and application are still subject to approval.

Question 49

We are exporter only and not placing medical device in Malaysia market. Do we need to register our medical device? Product not under own brand name.

Answer

Original Equipment Manufacturer (OEM) does not need to register product under MDA. For export, you must write an official letter to MDA. But if the medical device in place in Malaysia market, then it is a requirement to register the medical device and the establishment must have license.
