ADVISORY NOTE APPLICATION FOR CERTIFICATE OF FREE SALE (CFS) AND MANUFACTURING CERTIFICATE (MC)

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INTRODUCTION

The Medical Device Act 2012 (Act 737) has now been enforced as the transitional phase for registration has ended on June 2016. Therefore, there is a need for application for CFS and MC to align with Act 737 and also to facilitate the industry for export purposes.

You may need a CFS / MC to export medical devices. Please check first with the destination country to find out if you need the certificate. You don’t need this certificate in order to market within Malaysia. REVISION

1. Establishment license and Medical Device Registration

Local companies who wish to apply for Certificate of Free Sale (CFS) shall have establishment license and medical device registration.

2. Product that are under evaluation (application before 1st July 2016)

Status of product that is still under evaluation will no longer be stated in the certificate. Instead, their Form I.D will be written. This is made to facilitate industry in exporting medical device and avoid confusion with the related regulatory authority of other country.

However, MDA may make available to the public, information supplied to uphold impartiality. MDA may only release the name and address of Manufacturer and Authorized Representative and the product type that is registered with MDA. 3. Details of Medical Device

The new format for product details: ‘CLICK HERE ’

For CFS application, brand name and name of medical device must be stated for the CFS application. The brand name and name of medical device shall be same as in the medical device registration. 4. Medical device for export only.

Export only medical device may apply for Manufacturing Certificate or Export Permit. CFS is for the products that are currently available in Malaysia market. Since export only medical device is not available in Malaysia market, thus, it is not eligible for CFS.

Manufacturing Certificate is meant for medical device that is manufactured in Malaysia. For OEM who is not a brand owner of the medical device may apply for Manufacturing Certificate as alternative to Certificate of Free Sale. Declaration letter must be submitted with application stating that they are not the brand owner of the medical device and only act as manufacturing facility. 5. Fee Structure

The fee structure is as per below:

- One CFS application is only for one medical device registration number.

- All applications will be charged RM 100 per certificate (for one country).

- Validity: 2 years.

- Certificate inclusive of 1 attachment limited to 25 medical devices (for 1 page of attachment). Additional pages will be charged RM5.00 per page.

- Font type Arial and size 10 shall be used. 6. Additional information Additional information, particulars and documents requested by the Authority on the application shall be submitted by the applicant within 14 working days from the date of return of application. If the additional information, particulars or document of the application is not given by the applicant within the time granted (14 working days), the application shall be deemed to be withdrawn and shall not be further proceeded with, but without affecting the right of the applicant to make a fresh application. EFFECTIVE DATE

This revised criteria will be applied within 30 days from this announcement date.

For more information, please contact:

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