

CFS

Last Updated Sunday, 15 April 2018

Certificate of Free Sale / Manufacturing Certificate Local companies wishing to apply for Certificate of Free Sale (CFS) / Manufacturing Certificate (MC) please [CLICK HERE](#) for online application. ANNOUNCEMENT:

Conditions and fee structure:

- One CFS/MC application is only for 25 medical device registration numbers. If more than 25 registration number, please apply in another separately CFS/MC application form. This is not applicable to the non-registered medical device.
- All medical devices under 1 application must be from same manufacturer. If the manufacturer are different, please apply in different CFS/MC application form
- All applications will be charged RM 100 per registration number per country for 2 years validity; and all applications will be charged RM 300 per registration number per country for 5 years validity.
- Certificate is inclusive of 1 attachment. Additional pages will be charged RM5.00 per page. Each attachment will list up to 25 medical devices.
- Certificate will be issued based on per country.
- Font type Arial and size 10 shall be used for attachments.

Step for Application: 1. Section 1 is for applicant details; 2. Section 2 is for details of manufacturer; 3. Please fill the document on product list ([CLICK HERE](#)) and upload into section for document to be uploaded. Please upload only 1 attachment of product list in 1 application 4. Required documents to be uploaded:

| Documents | Certificate of free sale | Manufacturing Certificate (export only manufacturer) | Manufacturing Certificate (OEM manufacturer) |
|---|--------------------------|--|--|
| Registrar of Companies (ROC) certificate of applicant | Yes | Yes | Yes |
| establishment license | Yes | Yes | Not applicable |
| Proof of medical device registration (Notification letter / Acknowledgement letter/ Registration certificate) | Yes | Yes | Not applicable |
| Medical device list | Yes | Yes | Yes |
| Letter of declaration as OEM | Not applicable | Not applicable | Yes |
| Brochure | No | No | Yes |

(And any other additional information, particulars /documents as may be required) 5. Payment advice will be sent through email; 6. Bank draft must be submitted together with the payment advice; 7. Certificate will be given after payment is cleared.

PAYMENT:

- All fees shall be paid via bank draft. CASH WILL NOT BE accepted. We will not be responsible for the cash sent or brought to MDA;
- Kindly be informed that payment for CFS maximum of 5 submissions only can be combined together in one bank draft.
- The bank draft must be made payable to "KUMPULAN WANG PIHAK BERKUASA PERANTI PERUBATAN" and sent to MDA office;
- Information on CFS/MC serial number and Phone No. of the applicant must be written at the back of the bank draft but not in the table section;
- Payment must be made within 14 days after date of payment advice issued from MDA.

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 proceed with, but without affecting the right of the applicant to make a fresh application. Complete submission for certificate of free sales application will be processed within 14 working days The above requirement is subject to change from time to time. Any enquiries can be sent to Medical Device Authority (MDA) at the following address: Chief Executive

Medical Device Authority (MDA), Ministry of Health Malaysia

Level 6, Prima 9, Prima Avenue II,

Block 3547, Persiaran APEC, 63000 Cyberjaya, Selangor, MALAYSIA

Tel: +603-8230 0300 | Fax : +063-8230

0200 Or, please contact:

Tel: +603-8230 0300, Fax: +063-8230 0200

Email: cfs@mdb.gov.my

Contact Person: Mr Dinesh Vijian