

CFS

Last Updated Tuesday, 20 June 2017

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 5 medical device registration numbers. If more than 5 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
- Certificate is inclusive of 1 attachment. Additional pages will be charged RM5.00 per page. Each attachment will list up to 25 medical devices.
- Validity: 2 years.
- 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; 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 A copy of 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 5, No. 26, Menara Prisma, Precinct 3

62675 Putrajaya, MALAYSIA

Tel: +603-8892 2400 | Fax : +603-8892 2500

Or, please contact:

Tel: +603-8892 2400, Fax: +063-8892 2500

Email: cfs@mdb.gov.my

Contact Person: Ms Norfazila Zulkifli