

CFS

Last Updated Friday, 24 March 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:

Mesyuarat Anggota Pihak Berkuasa Peranti Perubatan on the 25th February 2015 has approved introduction of a fee for application of CFS and MC in accordance to Section 12. (1) f. Act 738. This introduction of fee is to cover the costs of CFS/MC issuance and its operation. The fee structure is as per below:

- One CFS/MC 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.

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 document to be uploaded: - Registrar of Companies (ROC) certificate of applicant; - A copy of establishment license; - Proof of medical device registration (Notification letter / Acknowledgement letter/ Registration certificate); - Local invoice; - Product list; (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 through bank draft. CASH WILL NOT BE accepted. We will not be responsible for the cash sent or brought to MDA;
- Kindly inform that payment for CFS maximum of 5 submissions only can be combined together in a 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 proceeded 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 requirements will subject to change from time to time. The 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