

Issuance of Certificates for Medical Devices for Export

When Japanese medical device manufacturers intend to export their products to foreign countries, certain countries require the manufacturers to submit the regulatory authority-issued certificate which authenticates that the products were manufactured in accordance with the Pharmaceutical Affairs Act (Act No. 145 of 1960).

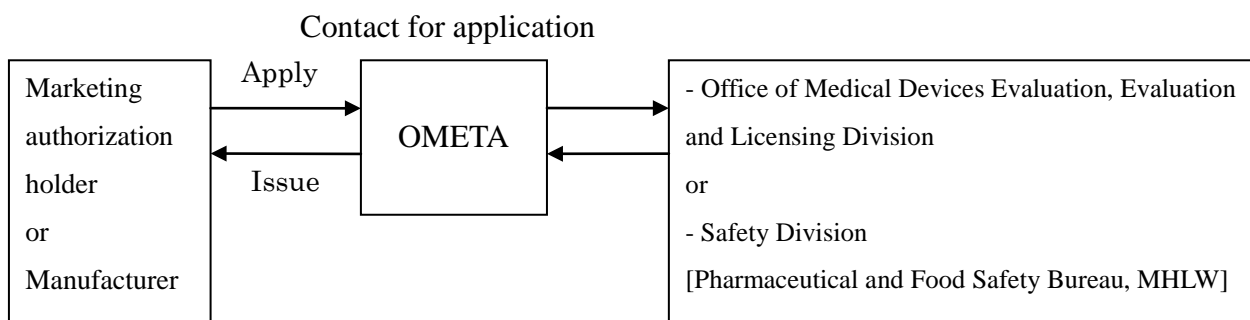
Those certificates are to be issued as specified in the “Issuance of Certificates of Drugs, etc. for Export,” the Administrative Notice jointly issued by the Evaluation and Licensing Division, Office of Medical Devices Evaluation and Safety Division of Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare (MHLW), dated October 3, 2005.

(1) Where Applications Should be Submitted

A medical device manufacturer who intends to obtain a certificate for medical devices (hereinafter referred to as "applicant") is required to submit the application form for certificates for medical devices and the form of a certificate pre-completed by the applicant, by delivering in person or by mail, to the **Overseas Medical Equipment Technical Assistants (OMETA)**. OMETA checks the validity of the information provided in the certificate form before forwarding the forms (with OMETA’s seal of confirmation affixed) to the relevant division or office according to the certificate category. OMETA charges a commission for the validity check of application documents.

Overseas Medical Equipment Technical Assistants (OMETA)
Address: Room No.173, 7F, Daiichi-Nishiwaki Bldg.,
1-58-10 Yoyogi, Shibuya-ku, Tokyo 151-0053, Japan
Phone: 03 3372 1793
Fax: 03 3372 1797
E-mail: info@ometa.or.jp
Website: <http://www.ometa.or.jp>

[Flow of Certificate Issuance]



(2) Documents to be submitted

- (a) Request form for the validity check of the certificate(s) to be issued by MHLW (OMETA-designated form)..... 1 copy
- (b) Application form for Certificates for Medical Devices (addressed to the Director of Office of Medical Devices Evaluation or Safety Division) 1 copy
- (c) Certificate form(s) (in English) necessary number of copies + 1 extra copy
Certificate form (in Japanese)..... 1 copy
- (d) Attachments
 - A copy of License for Marketing Authorization Holder
 - A copy of Manufacturer's License
 - A set of copies of Notification of Manufacturing or Importing Medical Devices for Export
 - A set of copies of product approval documents or product certificates (including copies of documents for approval or certification for partial changes, if applicable) or marketing notifications

(3) Application Form for Certificates of Medical Devices

Please refer to the OMETTA website for more information. (Japanese only)

(4) Certificates of Medical Devices

Applicants should submit the necessary number of copies of the certificate forms (one copy for one country, in principle) plus one extra copy for MHLW's record. Such a certificate form in English shall be accompanied by the corresponding Japanese certificate form.

In case where an applicant intends to obtain certificates for two or more products to submit to a single foreign government, it is recommended, where possible, that all the relevant products be included in one certificate rather than preparing a certificate for each product.

(5) Others

Please refer to the OMETTA website for more information. (Japanese only)