

CLARIFICATIONS ON GUIDELINES FOR IMPORT AND MANUFACTURE OF MEDICAL DEVICES

A large number requests for further clarifications on the guidelines issued by CDSCO for import and manufacturer of medical devices have since been received from individuals, Associations of medical devices, both from India and abroad. Beacuse of constraints of man power and time, it is not possible to communicate clarifications to each and every inquiry, and also because such doubts may be prevailing in the minds of many applicants, following clarifications and explanations on the guidelines are offered for general information

1. Medical devices family

For the purpose of registration of medical devices and calculating the fees to be deposited along with the application, a group or family of devices manufactured by or for the same manufacturer, having the same basic design, performance characteristic related to the device safety, effectiveness and intended use (including variation in sizes and shapes) would be considered as one single device. Further a device may also include package of various devices or sub systems that are required to be used together as a single functioning device.

2. Catheters

All sterile catheters would need registration and import license for import into India. Catheters may be clubbed together on the basis of end use, therapeutic purpose i.e. medical specialty in which used, and the material used in the manufacture irrespective of the design, size and shape. A single product registration fee shall be charge for such family of catheters.

3. Plant Master File

Plant Master File at serial number 3 under '(A) Applicant Details' may include the following information about the manufacturing site.

- (a) Location and layout plan of the premises
- (b) Flow chart or brief details of manufacturing process, quality control system to have inprocess controls over the quality of device manufactured and other related activities carried out at the premises.
- (c) System of conformity assessment followed by the manufacturer.
- (d) Details of approval or registration certificate issued by the Ministry of Health or National regulatory authorities controlling medical devices in the country where the manufacture is being carried out.
- (e) Annual production capacity of the device(s) applied for and other products manufactured at the same site.

4. Processing

The term processing at serial number 6 under ' (A) Applicant Details' would include any process or part of process for making, altering, finishing, packaging, labeling or breaking up being carried out after the device is imported in to India.

5. Qualitative and Quantitative Particulars of the constituents

The term Qualitative and Quantitative Particulars of the Constituent at serial number 6 under the heading '(B) Product Information', would mean brief description of the nature of the material used in the manufacture of the device and the standards to which these conform. Information in respect of the system followed by the manufacturer for checking the quality of the device and its accessories as a final product should also be given.

6. Labeling

Devices labeled as per GHTF guidelines or ISO specifications would by and large be accepted for the purpose of import into the country. However, specific variation in respect of any essential requirement under the Drug and Cosmetics Rules, if required, would be separately examined on merits.

7. Post Market Surveillance

Under heading '(F) Post Market Surveillance' the applicant is expected to give outline of the system which either has been put in place or is proposed to be set up to trace the device in case of complaint about its functioning or non conformance to the standards claimed for the device and the procedures followed or proposed to be followed by the applicant to assess any reported complaint in the use of the specific device. The applicant shall also give information to the license authority i.e. DCG (I) in the event of any adverse incidents reported by the users or hospitals while using the device and the procedures followed by the applicant in the event of recall of any specific lot or the device itself from the market.

8. Attestation of the power of attorney by Indian embassy

As India became signatory to the Hague Convention on 26th October 2004, the requirement of legislation of foreign public documents from the signatory countries may not be required.

9. Requirement of Undertaking under Part (G)

As the applicant is required to ensure the safety, effectiveness and conformance to the standards at the time of import into India, the separate requirement of undertaking under Part (G) may be dispensed with.