

FURTHER CLARIFICATIONS ON GUIDELINES FOR IMPORT AND MANUFACTURE OF MEDICAL DEVICES

Dated: 30/8/2006

- 1. Whether certain notified devices especially Orthopedic Implants which are imported as non-sterile devices and are sterilized by the hospitals before use fall within the ambit of the Gazette notification S.O.1468 dated 6/10/2005.**

The matter was examined by an expert committee and the accepted view is that if the end use of the notified device is as a sterile product, it will fall within the ambit of the notification. The import of such notified devices would therefore require registration and import license under the Drugs and Cosmetic Rules for their import.

- 2. Requirement of Batch Release Certificate for medicinal products.**

The Batch Release Certificate is required only in respect of those devices which contain biological products of animal and human origin.