

## Sectoral

### Medical devices

#### 1. What are the requirements to be a registered Notified body?

The requirements are laid down in Part I of Third Schedule of Medical Devices Rules, 2017.

#### 2. What is the process for classification verification with CDSCO or notified body prior to submission?

The Central Licensing Authority shall, classify medical devices referred to in Rule 2, based on their intended use and other parameters specified in the First Schedule. Based on the classification referred to in sub-rule (3), class wise list of medical devices shall be published on the website of the Central Drugs Standard Control Organization (CDSCO): Provided that the Central Licensing Authority may, from time to time, make additions or deletions in such list of medical devices or modify the class of any medical device. CDSCO has already displayed the list of medical devices with classification, which is dynamic in nature.

#### 3. What are the changes that require an applicant to make afresh Registration?

The following changes require a fresh registration: 1) Any change with respect to manufacturer (legal/actual) like change in constitution, change in name, change in address, etc. 2) Any change with respect to importer/Indian Agent like change in constitution, change in name, etc.

#### 4. How are IVDs classified in India under Medical Device Rules, 2017? Who will have the responsibility of doing Classification of IVD as per Class A/B/C/D?

IVDs are classified under Chapter II, Rule 4, Sub-rule (2) of Medical Device Rules, 2017 on the basis of parameters specified in Part II of the First Schedule, in the following classes, namely: i) Low risk - Class A, ii) Low moderate risk- Class B. iii) Moderate high risk- Class C. iv) High risk- Class D. Reference Rule 4 (3): This rule specifies that Central Licensing Authority shall classify the Medical Devices.

## 5. How much FDI is permitted under medical devices sector?

100% FDI is permitted under medical devices sector through automatic route.

## 6. What is the regulatory environment for medical devices in India as per 'New Medical Devices Rules'?

The Ministry of Health and Family Welfare on Thursday notified Medical Devices Rules, 2017, which are in conformity with Global Harmonisation Task Force (GHTF) framework. The rules have come into effect from January 01, 2018. The rules have been drafted with the intention to distinguish medical devices from pharmaceuticals for improved and well-defined regulation. The key highlights of the rules are: 1. Redefining 'medical devices', making it more comprehensive and easy to comprehend 2. Introduction of risk-based classification system for class-wise regulation 3. Single window clearance (online portal) for applications for import, manufacture, sale or distribution and clinical investigation 4. Establishment of product standards for medical devices to be conformed to 5. Rationalization of timelines for obtaining licenses required to market medical devices 6. Consolidation of registration certificate and import license into a single license 7. New regulatory framework for clinical investigation of medical device