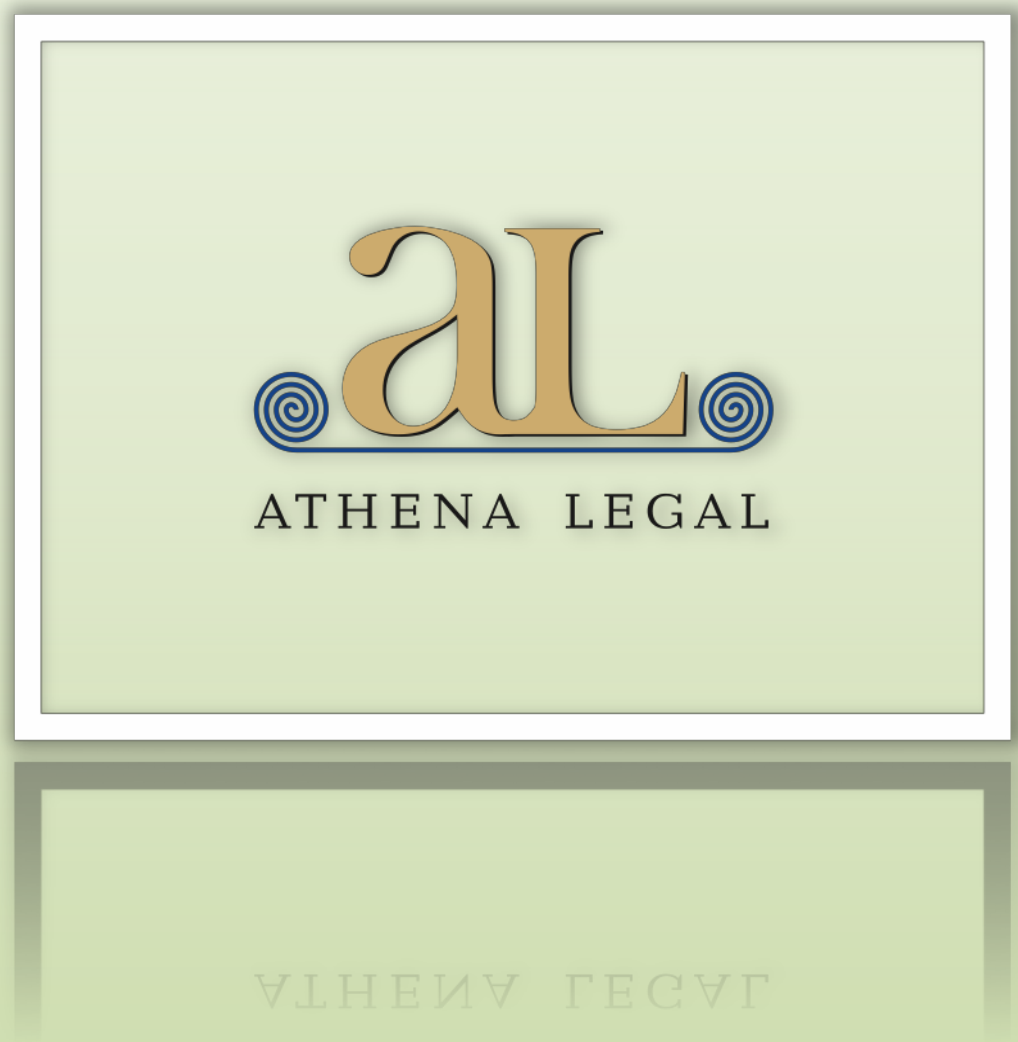
MEDICAL DEVICES REGULATION IN INDIA



CONTACT DETAILS

37 Link Road, First Floor, Lajpat Nagar-III,
New Delhi-110024
PH: 011-42004400/42004422
Email: correspondence @athenalegal.in

MEDICAL DEVICES REGULATION IN INDIA

The Indian medical industry is in focus due to the Covid-19 pandemic and the consequent increase in demand for test kits, ventilators and other medical equipment. The Medical Device Rules, 2017 (the '**Rules**') under the Drugs and Cosmetics Act, 1940 (the '**Act**') govern the Indian medical device industry. These Rules came into effect on January 1, 2018. The Rules are applicable in respect of:

i. Substances used for in vitro diagnosis and surgical dressings, surgical bandages, surgical staples, surgical sutures, ligatures, blood and blood component bag with or without anticoagulant covered under sub-clause (i) of section 3(b) of the Act;
ii. Substances including mechanical contraceptives (condoms, intrauterine devices, tubal rings), disinfectants and insecticides notified under sub-clause (ii) of section 3(b) of the Act;
iii. Devices notified from time to time under sub-clause (iv) of section 3(b) of the Act

The government had notified 37 categories of devices under the sub-clause (iv) Section 3(b) of the Act for stricter regulation under the Rules. The devices which did not come under the notified categories earlier, required a 'no objection certificate' from the Drugs Controller General of India ('**DCGI**'). However, a notification issued by the Government on February 11, 2020 which came into effect on April 1, 2020 has made it mandatory to register all devices and provided a new procedure for the same. On the same date government vide another notification amended the definition of Medical Devices which also came into effect on April 1, 2020.

Definition of Medical Devices

In accordance with the notification of February 11, 2020 by the Ministry of Health and Family Welfare ("**MOHFW**"), the definition of medical devices has been amended to mean – any instrument, apparatus, appliance, implant, material or other article, whether used alone or in combination, including software or an accessory, intended by its manufacturer to be used specially for human beings or animals by any pharmacological or immunological or metabolic means, but which may assist in its intended function by such means for one or more of the specific purpose of:

1. Diagnosis, prevention, monitoring, treatment or alleviation of any disease or disorder;
2. Diagnosis, monitoring, treatment, alleviation or assistance for, any injury or disability;

3. Investigation, replacement or modification or support of the anatomy or of a physiological process;
4. Supporting or sustaining life;
5. Disinfection of medical devices; and
6. Control of conception

Every device that comes under the purview of this definition is further classified by the Central Drugs Standard Control Organization ("**CDSCO**") on the actual risk; based upon the intended use and purpose:

- Class A – low risk medical devices such as absorbent cotton wools, surgical dressings, alcohol swabs, etc.
- Class B – low moderate risk devices such as thermometer, blood pressure monitoring device, disinfectants, etc.
- Class C – moderate high-risk devices such as implants, haemodialysis catheter etc.
- Class D – high risk devices such as angiographic guide wire, heart valve, etc.

The classification for the medical devices in these categories is based upon the Part I of the First Schedule of the Rules. All notifications regarding these can be accessed through the CDSCO website but for the time being, the classification has to be assessed by the applicant from the Part 1 of First Schedule of the Rules. The regulation with respect to manufacture of Class A & B devices is done through the State Licensing Authority, which is the State Drugs Controller and for Class C & D is done through the Central Licensing Authority, which is the DCGI.

Process for Registration

Through the notification dated February 11, 2020 the government has mandated the registration of all devices, except for the notified categories, through the procedure set down in Chapter IIIA of the Rules. In effect, combined with the amendment of the definition, all medical devices require registration for manufacture and import from April 1, 2020 onward. The manufacturers can simply submit their applications for grant of registration of the medical device through the CDSCO website (https://cdscomdonline.gov.in/NewMedDev/Homepage) by submitting the following information:

1. Name of company or firm or any other entity
2. Name and address of manufacturing site (for devices manufactured in India)

3. Details of the medical devices (Generic Name, Model No. Intended Use, Class of Medical Device, Material of Construction, Dimensions (if applicable), Shelf Life, Sterile or Non-Sterile Status, Brand Name (only if registered under India's trade mark law).
4. Certificate of compliance with respect to ISO 13485 standard accredited by National Accreditation Board for Certification of Bodies or International Accreditation Forum in respect of such medical device.
5. A duly signed undertaking stating that the information furnished by the applicant is true and authentic.
6. Specifications and standards of medical device (for imported devices only)
7. Free sale certificate from country of origin (only for imported devices)

After the submission, the registration is completed and the registration number is allotted which is required to be mandatorily printed on the medical devices. This is an expedited and simplier method for registration of those medical devices which did not fall under the previously notified 37 categories of medical devices. Regardless of the expediency, in order to ensure safety and quality standards, the Central Licensing Authority has been given the power to verify the documents at any point of time and investigate the quality or safety related failure or complaints.

One of the key features of this new regime under Chapter IIIA of the Rules is that the certificate of compliance with ISO-13485 (Medical Devices- Quality Management Systems) has been made mandatory for registration. Any importer or manufacturer shall now be required to mandatorily have this certification of ISO-13485. This will ensure that quality standards are maintained and no faulty devices are being sold in the market. It is also mandatory that this certification is maintained throughout the validity of license.

Apart from the registration of the medical device, for the manufacture or import, a separate license has to be obtained from the authorities. The same can be obtained within a period of 180-270 days from the date of application. The applications for the license are submitted through the portal of CDSCO mentioned above. For a license to import, the application has to be submitted to the DCGI. For the license to manufacture Class A & B medical devices, the application has to be submitted to the State Licensing Authority. For license to manufacture Class C & D medical devices, the application has to be submitted to the DCGI. The entire process for the same is regulated through the Rules as well.

Exemptions from Registration

To provide a smooth transition for registration of all medical devices which were previously unregulated, the government has made such registration voluntary for a period of 18 months from the commencement of the Chapter IIIA of the Rules. Further, the government has also added an exemption under the Eighth Schedule of the Rules for the complete application of the Chapter IIIA for a certain period of time, with respect to:

- Obtaining a compulsory license for manufacture or import of the Class A and Class B medical devices for a period of 30 months, which ends on August 11, 2022.
- Obtaining a compulsory license for manufacture or import of the Class C and Class D medical devices for a period of 42 months, which ends on August 11, 2023.

As such, after October 1, 2021 all medical devices will mandatorily have to be registered but the license for manufacture, import and sale of the medical devices not covered in the notified 37 categories, will be exempted till the time, as given above.

Consequence of Non-Compliance Before Deadline

If any manufacturer or importer fails to comply with the requirement for registration of the medical devices before October 1, 2021 or obtaining the license before August 11, 2022 for Class A & B, and August 11, 2023 for Class C & D, they will be held in violation of the Rules and the Act.

Following the implementation of the amendment of February 11, 2020, it will be easier for authorities to regulate the industry. The Legal Metrology (Packaged Commodity) Rules, 2011, requires every importer or manufacturer to state the date of import or manufacture, as the case may be, on the label of the medical device. Hence, if the registration number of the medical device is not present on the label of devices imported or manufactured on or after October 1, 2021, the DCGI can cease the device and take appropriate action against the importer or manufacturer. The violation of the Rules along with its amendment, can lead to initiation of criminal prosecution under the Act which can lead to imprisonment or fine or both. For example, manufacture or sale of substandard devices is punishable with imprisonment of 10 years, which may extend to life imprisonment.

DISCLAIMER

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37 Link Road, First Floor, Lajpat Nagar-III, New Delhi-110024

Phone: +91- 11- 4200 4400
E-mail: correspondence@athenalegal.in
Website: www.athenalegal.in