CDSCO updates list of Class A non-sterile and non-measuring devices

The Central Drugs Standard Control Organisation (CDSCO) has classified a total of 1,069 medical devices under the risk category of Class A (non-sterile and non-measuring), in order to fix the regulatory requirement related to registration and others in the country, for the benefit of the regulator and the industry stakeholders.

The list, an expansion to the previous list of around 803 devices, has been released on Class A (non-sterile and non-measuring) devices, which are exempted from the licensing requirements under the Medical Devices Rules, 2017, "provided that the manufacturer or importer shall obtain registration number for such devices from the CDSCO Online System for Medical Devices, under the provisions of Chapter IIIB of the Medical Devices Rules, 2017," said Dr Rajeev Singh Raghuvanshi, Drugs Controller General of India (DCGI).

The devices that fall under the new class include reusable abdominal scissors, reusable and single use abdominal support/belt/binders, reusable abdominal, ENT, orthopaedic surgical probe, devices related to acupressure, audiometric testing equipment, various adhesive pads and strips, pressure relief cushion, adult incontinence pants or diaper, alcohol swab, alternating-pressure bed mattress and its overlay, ambulance stretcher and ambulance stretcher loader, anaesthesia instrument table and mask stabliser among others, anatomical model for surgical planning, ankle cap, birthing bed and table, blood transfusion chair or couch, cerebral palsy walker, cervical pillow, chair cushion for paediatric use, among others.

The drug regulator said that while the listed devices and its intended use are included under the Class A non-sterile and non-measuring category the indented use are mentioned for the guidance to the applicant who intend to register the devices under the said category and devices can also have specific intended use specified by the manufacturer, provided that it is in similar lines to the intended use as mentioned in the regulator's risk classification list.

"This list is dynamic and is subject to revision from time to time under the provisions of the Medical Devices Rules, 2017," added the regulator. The variants of medical devices which have measuring function or supplied in sterile state, shall not be considered under the particular risk classification, it added.

It may be noted that the CDSCO has released a draft update on the risk based classification list in January, 2025, revisiting the prevailing list and adding new entries including the Interventional Radiology, Radiotherapy, Oncology, and Class A (non-sterile and non-measuring) medical devices, seeking comments from the stakeholders.

According to the Rule 4 of Chapter II of the MDR, 2017, the medical devices other than in vitro diagnostic medical devices has been classified on the basis of various parameters mentioned in the Part I of the First Schedule of the Rules, as Class A comprising low risk devices, Class B for low moderate risk devices, Class C for moderate high risk products, and Class D for high risk

products. Similar classification has been made for the in vitro diagnostic medical devices, based on Part II of the First Schedule of the Rules.

The Central Licensing Authority (CLA) has the authority to classify medical devices based on the intended use of the device and other parameters specified in the First Schedule of the Rules. The rules also provide powers to the CLA, from time to time, to make additions or deletions in such lists of medical devices or modify the class of any medical device.

The classification helps the regulator to better regulate the sector, by issuing licenses, ensuring regulatory compliance across the categories, and bringing in international standards of regulations.

The government has notified all medical devices to be regulated under the MDR, 2017, in February, 2020 following various discussions on the need to regulate the sector, which has been seeing growth in the recent years.

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