CDSCO Issues Revised Risk Classification List for Cardiovascular and Neurological Medical Devices

In India, the Ministry of Health and Family Welfare ("**MoHFW**") regulates pharmaceuticals, drugs, medical devices, and cosmetics. Moreover, the Central Drugs Standard Control Organization ("**CDSCO**") is India's national regulatory body for pharmaceuticals, drugs, medical devices, and cosmetics, and it ensures their safety and quality. The MoHFW published the Drugs and Cosmetics Act, 1940 ("**DCA**") to regulate the import, manufacture, distribution, and sale of drugs and cosmetics in India. It is pertinent to note that the CDSCO published the Medical Device Rules, 2017 ("**MDR**") under the DCA, to specifically regulate medical devices.

As per **Rule 4** of the MDR, medical devices are required to be classified via a risk based classification and on the basis of parameters specified in **Part I of the First Schedule** of MDR. We note that the different types of classification of a medical device is as follows:

- Low risk- Class A;
- Low moderate risk- Class B;
- Moderate high risk- Class C;
- High risk- Class D

Based on the classification of the medical devices, a class wise list of medical devices is also published on the website of the CDSCO. The classification provides a clear understanding of the regulatory requirements for the medical device in the respective class. Moreover, it allows the manufacturers to plan the product development, testing, and approval processes of their medical devices.

To comply with Rule 4 of the MDR, on **3 September, 2020**, the CDSCO issued a notice having – File No: 29/Misc/03/2020-DC (200), titled "*Classification of non-notified Medical Devices*". The notice contains a draft classification list that divides medical devices into 24 categories. Cardiovascular and neurological medical devices are two of the categories included in these 24 categories of medical devices.

The Timeline Pertaining to Classification of Cardiovascular and Neurological Medical Devices

- On **1 November, 2017,** the CDSCO issued a notice having – File No: 29/Misc/3/2017-DC (292), titled "*Classification of medical devices and in vitro diagnostic medical devices under the provisions of the Medical Devices Rules, 2017*". The risk classification lists issued under the said notice includes several cardiovascular and neurological medical devices.

- Further, on **26 July, 2021,** the CDSCO issued a notice, having – File No: 29/Misc./03/2020-DC (159) titled "*Classification of medical device pertaining to **Cardiovascular** under the provisions of Medical Devices Rules, 2017*", which lists 36 cardiovascular medical devices, along with their risk classification and intended use.

- Subsequently, the CDSCO on **27 September, 2021,** issued a notice having – File No: 29/Misc./03/2020-DC (201) titled "*Classification of Medical Device pertaining to **Neurological** under the provisions of Medical Devices Rules, 2017*", which lists the risk classification and intended use of 110 neurological medical devices.

- Thus, even though cardiovascular and neurological medical devices have been classified earlier (*as provided above*) based on the risks they pose, the CDSCO, on **April 1, 2025,** issued a notice having – File No: MED-16015(11)/1/2025, with the title - "***Revision of risk-based classification** lists of Medical devices in the categories of Cardiovascular and Neurological*", which seeks to reclassify cardiovascular and neurological medical devices, ("**Reclassification Notice**").

- The Reclassification Notice provides for a draft of the classification lists which includes a total of 553 devices, which includes 351 cardiovascular and 202 neurological medical devices. It can be reasonably inferred that the attempt of the CDSCO to reclassify cardiovascular and neurological medical devices shall undoubtably impact all the concerned manufacturers, importers, resellers, and distributors of cardiovascular and neurological medical devices in India. Therefore, in light of the same, the CDSCO has requested all the concerned associations/stakeholders to submit their feedback/comments on the revised classifications enshrined under the Reclassification Notice via filling the Google form at https://forms.gle/62xF3BtXWC5pgD3TA by **30 April, 2025**.

***Important Note**: Industry experts and stakeholders are advised to carefully check the reclassification of the cardiovascular and neurological medical devices under the draft list mentioned in the Reclassification Notice to ascertain the impact on their medical devices.*

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