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CDSCO notifies regulation of medical devices from December

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Central Drugs Standard Control Organization (CDSCO) has published a gazette notification on recently with the proposal defining all medical devices as drugs and seeking public comments within one month.

In a draft notification issued on Friday, the Union Ministry of Health and Family Welfare said, “It plans to define all medical devices, which were earlier not under the purview of the apex drug controller, as drugs under the Drugs and Cosmetics Act from December 1.”

As per the notification, Once the final notification is in place, all medical devices including software, equipments, accessories and contraceptives will be regulated under Drugs and Cosmetics Act and firms will have to seek an approval from the the Drugs Controller General of India to manufacture, import and sell any medical devices in the country.

Pavan Choudary Director General and Chairman, Medical Technology association of India (MTaI) said, “The Health Ministry's proposal to regulate all medical devices will allow Indian patient the access to quality medical devices also and put a check on garage manufacturing. CDSCO under the Ministry of Health & Family welfare has the most experience and over time have built the expertise to regulate
this intricate medical device sector. Bringing all medical devices under regulation has been a long-pending demand from the industry and it is encouraging to see the government taking cognizance of industry concerns."

He also added, “The domestic industry would also benefit from this regulatory pathway, as compliance with global standards will open up access to global markets for more domestic manufacturers-and not just the big ones. This Global harmonization (for which a liberal adjustment time is being given), will go a long way in encouraging foreign investments -facilitating Make in India. It will also boost FDI which had recently fallen drastically in this sector.”