4534

Directorate of Food & Drugs Administration

Government of Goa

Dhanwantari, Opp. Shrine of the Holy Cross, Bambolim – Goa – 403 202

PRESS NOTE

License compulsory for all Class A and Class B medical devices w.e.f. 01/10/2022

Central Government vide Gazette Notification GSR 102(E) dated 11/02/2020; has notified that for manufacture of all Class A & Class B medical devices license will be mandatory under Medical Devices Rules 2017 with effect from **01.10.2022**; copy of above Gazette notification is uploaded on the official website of FDA www.dfda.goa.gov.in. Also enclosed herewith.

The term medical device means any device intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals.

Further Central Government vide Notification No. S.O. 648(E) dated 11/02/2020 has specified the following devices intended for use in human beings or animals as drugs with effect from the 1st day of April, 2020, namely:-

All devices including an instrument, apparatus, appliance, implant, material or other article, whether used alone or in combination, including a software or an accessory, intended by its manufacturer to be used specially for human beings or animals which does not achieve the primary intended action in or on human body 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 purposes of –

i. Diagnosis, prevention, monitoring, treatment or alleviation of any disease or disorder;
ii. Diagnosis, monitoring, treatment, alleviation or assistance for, any injury or disability;
iii. Investigation, replacement or modification or support of the anatomy or of a physiological process;
iv. Supporting or sustaining life;
v. Disinfection of medical devices; and
vi. Control of conception.

Under the Medical Devices Rules 2017, the medical devices are classified based on the risk factor as Class A (low risk), Class B (Moderate risk), Class C (moderate high risk), and Class D (high risk).Out of the above manufacturers of Class A & Class B medical devices are licensed by State Licensing Authority and manufacture of Class C & Class D medical devices are licensed by Central Licensing Authority

All the concerned manufacturers are requested to obtain license for manufacturing of Class A & Class B medical devices by visiting online medical device portal https://cdscomdonline.gov.in.

Jyoti J. Sardesai
Director, Food & Drugs Admn.