

F. No. IVD/Misc/030/DCGI/18
Government of India
Central Drugs Standard Control Organization
FDA Bhawan, Kotla Road,
New Delhi-110002

To

Dated: 27 FEB 2018

All State/UT's Drugs Controller,

Sub: Designation of Central Medical Device Testing Labs & Medical Device Testing Officer for Medical Devices including In-Vitro Diagnostic medical device under Medical Device Rules, 2017- regarding.

Sir,

This is with reference to Rule-19 in chapter-III, of Medical Device Rule, 2017, published vide MOHFW notification No GSR 78(E) dated 31st January, 2017 implemented from 1st January 2018, wherein it is prescribed that the Central Government may, by notification, may also designate any laboratory having facilities for carrying out test and evaluation of Medical Devices, as Central Medical Devices Testing Laboratory for the above mentioned purposes with the proviso that no Medical device Testing laboratory, shall be so designated unless it has been duly accredited by the National accreditation Board for testing and calibration laboratories (i.e. NABL).

As per Rule-18 (1) the Central Government may designate a Government Analyst appointed under Section 20 of the Act as a Medical device Testing Officer.

Therefore, for expeditious fulfillment of requirements of rules by the testing laboratories of the State/ UTs, you are requested to send the proposal to get your laboratories designated as Central Medical Device Testing Laboratory for testing and evaluation of the Medical Devices by sending the proposal alongwith list of medical device products (amongst the 23 medical devices) (**Annexure-1**), for which your laboratories may be designated (based on NABL Accreditation) by Central Government for testing.

Further, it is also requested to send the names of concerned Govt. Analyst(s) appointed under Section 20 of Drugs and Cosmetic Act, who may be designated as Medical Device Testing Officer (MDTO) for the purpose of testing of medical devices for which a medical device testing laboratory is proposed to be designated under Medical Devices Rules, 2017, in the tabulated form in following format by return mail on dcu@nic.in and ddcimd-cdsco@nic.in by 1st Mar. 2018.

Sr. no.	Name & address of State/ UT Lab.	Products (out of 23 attached) for which designation as MDTL is proposed. (Annexure-1)	Whether lab. is NABL Accredited or Not?	Name of Govt. Analyst(s) appointed under Section 20 (to be designated as Medical Device Testing Officers) with Qualification, experience in relevant testing

Yours faithfully,



(Dr. S Eswara Reddy)
Drugs Controller General (India)

Copy to:

All Zonal and Sub Zonal Offices of CDSCO for, peruse the matter with the concerned SLAs.