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

Dated: 01 MAR 2018

Sub: Proposal invited for Designation of Central Medical Device Testing Lab for Medical Devices including In-Vitro Diagnostic Medical Device under Medical Device Rules, 2017-regarding.

It is desired in light of new Medical Device Rules-2017, published vide MOHFW notification No GSR 78(E) dated 31st January, 2017 effective from dated 1st January 2018 that CDSCO/CLA/SLA shall have updated information of laboratories involved in testing of medical device & in vitro diagnostics, as based on these laboratory reports, decision on performance evaluation of these products are made by stakeholder/regulator.

In this regard, it is also required to get such laboratories shall get registered under Rules 81-86 of chapter X of MDR-2017, if they are involved in Medical device/IVD's testing on the behalf of stakeholder.

Further, Rule-19 in chapter-III, of Medical Device Rule, 2017, prescribes that the Central Government may, by notification, may also designate any laboratory having facilities for carrying out test and evaluation of Medical Devices including In vitro Diagnostics medical device, 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).*

Therefore, NABL Accredited laboratories which are having capacity & capability for testing & evaluation of the Medical device including In Vitro Diagnostics may get registered with CDSCO & inform details of their activities. Similarly those labs, who are willing to get designated as Medical Device Testing Laboratories under said rules shall communicate their details about which Medical Device/IVD's can be tested at their laboratories along with person involved in the testing. This information is being sought in light of MDR-2017 & those labs which are found suitable may officially be designated as Central Medical Device testing lab for the purpose of testing & evaluation.

Details/Proposal in this regard, along with the copy of documents/information listed in Annexure-1 may be forwarded to this office (Central Drugs Standard Control Organization, Medical Device & Diagnostic Division, FDA Bhawan, Kotla Road, New Delhi-110002 as well as mail on dci@nic.in and ddcimd-cdsco@nic.in by 15st Mar. 2018.

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

To

1. All NABL Accredited laboratories involved in testing of medical device including In Vitro Diagnostics
2. All Association for Medical Device & In vitro Diagnostics
3. IDMA/OPPI/IPA
4. All State/UT's Drugs Controller/ All Zonal and Sub Zonal Office of CDSCO with request to coordinate & facilitate the process of labs identification/registration/designation as mentioned above
5. CDSCO Website for information for all stake holder

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Annexure-1

1. Covering Letter mentioning the Name & address of testing Institute/Hospital/diagnostic lab on the letter head, duly sign and stamped by the Director/Head of Organisation
2. Self attested copy of authorization letter to the person issued by the Director/ Company Secretary/ Partner/ Owner
3. Valid copy of NABL Certificate along with the annexure (Scope of test for which it is accredited)
4. Copy of testing Protocol and testing method for each of the testing parameter
5. List of Equipments/Apparatus/Instruments/Analyser along with the calibration status and manufacturer details
6. Number of sample required for each testing along with proposed testing fee
7. Time duration for the testing report
8. Name & Designation of the competent person for each of testing including his/her Qualification, experience in relevant testing
9. Expression of Interest (EOI) - that you would like to be designated as Medical Device or In Vitro Diagnostic Testing Laboratory.

Note:

All information provided shall be authenticate & verifiable. Further applicant shall willing to sign agreement that there will not be conflict of interest for purpose of testing & evaluation. Additionally applicant may also provide any additional information describing operational ability/other accreditation/ approval/licenses/agreement held by applicant for testing facility.