No. 29/Misc/03/2018-DC(59)
Government of India
Central Drugs Standard Control Organisation
Directorate General of Health Services
Ministry of Health & Family Welfare
(Medical Device & Diagnostic Division)

FDA Bhawan, Kotla Road,
New Delhi-110002, Dated 08 AUG 2018

To,

All State Drugs Controller
All Zonal/ Sub Zonal office of CDSCO

Sub:- Grant of additional products & certificates like i.e. Market standing certificate, Non-conviction certificate and performance certificate etc. w.r.t. Medical Devices and In-vitro Diagnostics - Regarding

Sir/ Madam

It is to inform that there has been various queries with regard to modalities and issuing authority for grant of additional products & various certificates like Non-conviction certificate, validity certificate, Market standing certificate, Performance certificate etc. for Medical Device & In Vitro Diagnostics.

In this regard, this office has already clarified in Frequently Asked Questions on Medical Device Rules-2017 at question no. 5, 62, 63 and 64, published on CDSCO Website, which are reproduced below:

Q.No.5 What will be procedure to obtain additional products on existing valid licences, in similar category of Medical Devices/IVD's after 01.01.2018?

Ans: Application form, fees and documents will have to be submitted on new Medical Device portal as per MDR-2017 to obtain the new licence

Q.No.62 Whether GMP compliance and GMP certification is applicable to medical devices and IVDs as per Medical Devices Rules, 2017 as it ask for compliance to Quality Management System (QMS) & there is no mention of need for compliance to GMP?

Ans: As per Medical Devices Rules, 2017, there is no mention of requirement for compliance to GMP, but there is need for compliance to QMS and other rules. Therefore, now, there is no requirement of GMP certificates for Medical Devices & IVDs.

Q.No.63 Despite no mention in rule for domestic purposes, if requested by importing country, who will issue the WHO GMP certificate for medical devices and IVDs ?

Ans: Licensing Authority who has issued the valid license to manufacture for sale will continue to issue WHO GMP certificate (Only on the request of importing country)

Q.No.64.. Who will issue the other certificates like Non-Conviction Certificate, Validity Certificate, Market Standing certificate etc. which are not mentioned in rules but are required on request of procurement / tendering agencies?

Ans: The Licensing Authority who has issued license shall issue such certificates.

Further in case of any query, it is requested to refer to FAQ for ensuring smooth functioning of MDR-2017 and solving the stakeholder's queries.

Yours faithfully,

VGS

(Dr. V.G. Somani)
Joint Drugs Controller (I)

Copy to :-

1. AIMED- 901-902, Narain Manzil, 23, Barakhamba Rd, Barakhamba, New Delhi- 110001
2. ADMI- 424, New GIDC, Kablipore, Navsari, Gujarat 396424
3. ASSOCHEM- 5, Sardar Patel Marg, Chanakyapuri, New Delhi, Delhi 110021
4. Confederation of Indian Industry (CII)
5. The Advanced Medical Technology Association (AdvaMed)
6. The Federation of Indian Chambers of Commerce and Industry
7. CDSCO, Website