

File No: 29/MISC/3/2017-DC (288)
Drugs Controller General (India)
Directorate General of Health Services
FDA Bhawan, Kotla Road, New Delhi

Date: 06 AUG 2018

NOTICE

Subject: List of Notified Bodies registered with CDSCO under MDR, 2017- regarding

As you are aware that Medical Device Rules 2017 has already been published vide G.S.R. 78 (E) dated 31.01.2017 under Drugs and Cosmetic Act to regulate the manufacture, import, sale and distribution of the medical devices and said rules are effective from 01.01.2018.

The notified bodies registered with CDSCO under provisions Medical Devices Rules, 2017 to carry out audit of manufacturing site under the provisions of said rules.

In this connection, following Notified Bodies have been registered with CDSCO:

1. M/s Intertek India Pvt. Ltd.,

E-20, Block B1, Mohan Cooperative, Industrial Area E-20,
Block B1, Mohan Cooperative, Industrial Area New Delhi (India) - 110044
Telephone No.: 011-41595475, 9310412823 Fax: 011-41595460
E-Mail: kamal.gupta@intertek.com

2. M/s TUV Rheinland India Pvt. Ltd,

82/A West Wing, 3rd Main Road 82/A West Wing,
3rd Main Road Electronic City (India) - 560100
Telephone No.: 080- 46498030 Fax: 080 4649 8042
E-Mail: guruprasad.hc@ind.tuv.com

3. M/s TUV Sud South Asia Pvt. Ltd,

TUV SUD House, Off Saki Vihar Road, Saki Naka,
Andheri (East), Mumbai-400072.
Telephone No.: 022-49035508 Fax: 022-49035508
E-Mail: info@tuv-sud.in

4. M/s, Dnv GI Business Assurance India Private Limited

Equinox Business Park, Tower 3, 6th Floor, BKC, LBS Road,
Kurla West, Mumbai-400070 (India),
Telephone No.: 022-61768909 Fax: 022-61768950
E-Mail: JOHER.JERWALLA@DNVGL.COM

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

To,

IT Cell for uploading the information on CDSCO website