File No. 29/Misc/3/2017-DC (288) Government of India Ministry of Health & Family Welfare Directorate General of Health Services Central Drugs Standard Control Organisation (Medical Devices Division)

Date: U 9 MAR 7023

NOTICE

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

As you are aware that Medical Devices 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

Registration Certificate No. RC/NB-000001

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 Registration Certificate No. RC/NB-000002

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
Registration Certificate No. RC/NB-000003

4. M/s, Dnv Gl 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 Registration Certificate No. RC/NB-000004

5. M/s, BSCIC CERTIFICATIONS PVT. LTD.

Flat No. 6, Shiv Shakti, GH-15, Sec-21C, Part-3,

Faridabad-121001 (India),

Telephone No: 01294175513, Fax: 01294175513

Registration Certificate No. RC/NB-000006

6. M/s, MTIC INTERCERT SAAR INDIA PRIVATE LIMITED

No 122/1, 3rd Main Road, Margosa Road, Malleswaram, Bangalore-560003 (India),

Telephone No: 918041285610, Fax: 918041285610

Registration Certificate No. RC/NB-000007

7. M/s, Zenith Quality Assessors Pvt. Ltd.

No. 306, 4th Floor, Sai Apex, Viman Nagar,

Pune-411014 (India),

Telephone No: 20-41322042, 41322043, Fax: 20-41322042, 41322043

Registration Certificate No. RC/NB-000008

8. M/s International Certification Services Pvt. Ltd.

22/23, Goodwill Premises, Swastik Estate, 178 CST Road,

Kalina, Santacruz East, Mumbai – 400098 (India)

Telephone No.: 02242200900, 02226507777, Fax: 02242200900,

02226507777

Registration Certificate No. RC/NB-000009

9. M/s, TUV India Private Limited

801, Raheja Plaza, LBS Road, Ghatkopar West,

MUMBAI-400086 (India),

Telephone No: 22-66477000, Fax: 22-66477000

Registration Certificate No. RC/NB-000010

10. M/s ACM EMB Private Limited

210, 2nd FIR Syndicate House, Old Rohtak Road,

Inderlok, New Delhi - 110035 (India)

Telephone No.: 09029527001, Fax: 0902957001

Email: INFO@ACMCERT.IN

Registration Certificate No. RC/NB-000011

11. M/s IRCLASS Systems and Solutions Private Limited,

52A, Adi Shankaracharya Marg, Powai,

Mumbai - 400072 (India)

Telephone No.: 09167178393, Fax: 09167178393

Email: SHASHINATH.MISHRA@IRCLASS.ORG

Registration Certificate No. RC/NB-000012

12. M/s UL India Pvt. Ltd., 24, Kalyani Block, 3rd Floor EPIP Zone, Whitefield, Bangalore – 560066 (India) Telephone No.: 08041384400, Fax: 08041384400 **Registration Certificate No. RC/NB-000013**

13. M/s, Quality Austria Central Asia Private Limited SECOND FLOOR, BLOCK 201 TOWER C ATS BOUQUETS,

Noida - 201301 (India)

Telephone No.: 08685831284, Fax: 08685831284 Email: DIGVIJAY.SINGH@QACAMAIL.COM Registration Certificate No. RC/NB-000014

> (Dr. Rajeev Singh Raghuvanshi) Drugs Controller General (India)

To, IT Cell for uploading the information on CDSCO website.