FORM MD-15

[See sub-rule (1) of rule 36]

Licence to Import Medical Device

Licence No. : IMP/IVD/2020/000608

1. M/s TULIP DIAGNOSTICS PRIVATE LIMITED, D-3, D-4, ANTONIO DO REGO BAGH, ALTO SANTACRUZ, BAMBOLIM, , North Goa, Goa (India) - 403202 Telephone No.: 08322458546 FAX: 08322458544 is hereby licenced to import the medical device(s) manufactured by overseas manufacturer having manufacturing site as specified below.

2. Details of overseas manufacturer and manufacturing site under this licence

S.No	Name and Address of Manufacturer	Name and Address of Manufacturing Site
1	Legal Manufacturing Site : M/s Suzhou Sym-Bio Lifescience Co., Ltd.,, No. 115, North Tai Ping Road, Taicang, Jiangsu Province, 215400, Country: China Telephone No.: 86 0512 53378788 FAX: 86 0512 53378788 E-Mail : service.symbio@perkinelmer.com	Actual Manufacturing Site : M/s Suzhou Sym-Bio Lifescience Co., Ltd.,, No. 115, North Tai Ping Road, Taicang, Jiangsu Province, 215400, Country: China Telephone No.: 86 0512 53378788 FAX: 86 0512 53378788 E-Mail : service.symbio@perkinelmer.com

3. Details of medical device(s):

S.No	Medical Device Details
1	1. Generic Name :PerkinElmer® Nucleic Acid Extraction Kit 2. Brand Name(if registered under the Trade Marks Act, 1999) :PerkinElmer® Nucleic Acid Extraction Kit 3. Class of Medical Device :Class C 4. Shelf Life :12 MONTHS 5. Sterile/Non-sterile:Non-Sterilized 6. Intended Use :The PerkinElmer® Nucleic Acid Kit is designed for DNA/RNA extraction and purification from oropharyngeal swab, nasopharyngeal swab, plasma and serum specimens using magnetic beads. The kit is intended to be used for in vitro diagnostics with PerkinElmer diagnostic assays, for example the PerkinElmer® SARS-CoV-2 Real-time RT-PCR Assay. 7. Material of Construction: NA 8. Dimension: 48 Tests: 100*107*90 mm; For 480 Tests: 190*168*174 mm 9. Model No. :NIL

VENUGOPAL GIRDHARILAL SOMANI

Digitally signed by VENUGOPAL GIRDHARILAL SOMANI
DN: c=IN, o=MINISTRY OF HOME AFFAIRS, ou=CDSCO DGHS, postalCode=431401, st=Maharashtra, 2.5.4.20=173d03345dfc62d4896323791a471bfdaa9f0b2bea56c83bfbbe2154e39f8b1af7, cn=VENUGOPAL GIRDHARILAL SOMANI
Date: 2020.06.18 12:33:08 +05'30'

4. The authorised agent M/s TULIP DIAGNOSTICS PRIVATE LIMITED, D-3, D-4, ANTONIO DO REGO BAGH, ALTO SANTACRUZ, BAMBOLIM, , North Goa, Goa (India) - 403202 Telephone No.: 08322458546 FAX: 08322458544will be responsible for the bussines activities of the overseas manufacturer, in India in all respects.

5. This licence is subject to the provisions of the Medical Devices Rules, 2017 and conditions prescribed therein.

VENUGOPAL GIRDHARILAL SOMANI

Digitally signed by VENUGOPAL GIRDHARILAL SOMANI
DN: c=IN, o=MINISTRY OF HOME AFFAIRS, ou=CDSCO DGHS, postalCode=431401, st=Maharashtra, 2.5.4.20=173d03345df62d489632379a1471bfdae9f0b2bea56c83bfbbe2154e399b1af7, cn=VENUGOPAL GIRDHARILAL SOMANI
Date: 2020.06.18 12:33:16 +05'30'

Place: New Delhi

Central Licensing Authority