



सत्यमेव जयते

FORM MD-5

[See sub-rule (4) of rule 20 and sub-rule (6) of rule 20]

Licence to Manufacture for Sale or for Distribution of Class A or Class B medical device

Licence Number: MFG/IVD/2019/000003

1. M/s MOLBIO DIAGNOSTICS PVT. LTD, H.NO. 13, SAGAR SOCIETY, DONA PAULA, PANAJI NORTH GOA, 403 004TISWADI, South Goa, Goa (India) - 403004 Telephone No.: 08322783267 FAX: 08322783139 has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at M/s Molbio Diagnostics Pvt. Ltd., Plot No. L-46, Phase II D, Verna Industrial Estate, Verna, South Goa, Goa (India) - 403722 Telephone No.: 09960590604 FAX: 0832 2783267

2. Details of medical device(s) [Annexed]

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

ANNEXURE

S.No.	Details Of Device(s)
1	<p>Generic Name:Chip-based Real Time PCR Test for HLA-B27</p> <p>Model No.:NIL</p> <p>Intended Use:Truenat™ HLA-B27 is a chip-based Real Time Polymerase Chain Reaction (PCR) test for the qualitative detection of HLA-B27 in human blood specimen and aids in the diagnosis of HLA-B27 typing. Truenat™HLA-B27 runs on the Truelab™ Real Time Quantitative micro PCR Analyzers.</p> <p>Class of medical device:Class B</p> <p>Material of construction:A. Individually sealed pouches, each containing: 1. Micro PCR chip preloaded with dried down proprietary buffer and sealed with inert polymer. 2. Microtube containing freeze dried biomix comprising Oligonucleotides (primers and probes specific to HLA-B27 and internal control DNA), dNTPs, DNA polymerase in proprietary buffer. 3. DNase & RNase free pipette tip. 4. Desiccant pouch B. Package insert</p> <p>Dimension(if any):</p> <p>Shelflife:24 months</p> <p>Sterile or Non sterile:Non-Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999):Truenat™ HLA-B27</p>

Place: Directorate of Food & Drugs Administration,
Bambolim- Goa.

Date26-Mar-19

State Licensing Authority