



सत्यमेव जयते

## FORM MD-9

[See sub-rule (1) rule 25]

Licence to Manufacture for Sale or for Distribution of Class C or Class D medical device

Licence Number: MFG/IVD/2019/000018

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. The names, qualifications and experience of the competent technical staff responsible for the manufacture and testing of the above mentioned medical device(s): As per records maintain by the manufacturer

4. 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 Plasmodium falciparum</p> <p>Model No.:NIL</p> <p>Intended Use:Truenat™ Malaria Pf is a Chip-based Real Time Polymerase Chain Reaction (PCR) test for the quantitative detection and diagnosis of Plasmodium falciparum (Pf) in human blood specimen and aids in the diagnosis of infection with Malaria caused by Plasmodium falciparum (Pf). Truenat™ Malaria Pf runs on the Truelab™ Real Time Quantitative micro PCR Analyzers.</p> <p>Class of medical device:Class C</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 Plasmodium falciparum and internal control DNA), dNTPs, DNA polymerase in proprietary buffer. 3. DNase &amp; 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™ Malaria Pf</p>

2	<p>Generic Name:Chip-based Real Time Duplex PCR Test for Plasmodium vivax and Plasmodium falciparum</p> <p>Model No.:NIL</p> <p>Intended Use:Truenat™ Malaria Pv/Pf is a Chip-based Real Time Polymerase Chain Reaction (PCR) test for the quantitative detection of Plasmodium vivax and Plasmodium falciparum in human blood specimen and aids in the differential diagnosis of infection with Malaria caused by Plasmodium vivax and Plasmodium falciparum. Truenat™ Malaria Pv/Pf runs on the Truelab™ Real Time Quantitative micro PCR Analyzer.</p> <p>Class of medical device:Class C</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 Plasmodium vivax and Plasmodium falciparum and internal control DNA), dNTPs, DNA polymerase in proprietary buffer. 3. DNase &amp; 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™ Malaria Pv/Pf</p>
3	<p>Generic Name:Chip-based Real Time PCR Test for Mycobacterium tuberculosis</p> <p>Model No.:NIL</p> <p>Intended Use:Truenat™ MTB is a Chip-based Real Time Polymerase Chain Reaction (PCR) test for the quantitative detection and diagnosis of Mycobacterium tuberculosis (MTB) in human pulmonary and EPTB specimen and aids in the diagnosis of infection with MTB. Truenat™ MTB runs on the Truelab™ Real Time micro PCR Analyzers.</p> <p>Class of medical device:Class C</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 Ribonucleoside - diphosphate reductase gene of Mycobacterium tuberculosis and internal control DNA), dNTPs, DNA polymerase in proprietary buffer. 3. DNase &amp; 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™ MTB</p>

4	<p>Generic Name:Chip-based Real Time PCR Test for Salmonella spp.</p> <p>Model No.:NIL</p> <p>Intended Use:Truenat™ Salmonella is a Chip-based Real Time Polymerase Chain Reaction (PCR) test for the qualitative detection and diagnosis of Salmonella in human blood and aids in the diagnosis of infection with Salmonella. Truenat™ Salmonella runs on the Truelab™ Real Time micro Quantitative PCR Analyzers.</p> <p>Class of medical device:Class C</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 Salmonella spp. and internal control DNA), dNTPs, DNA polymerase in proprietary buffer. 3. DNase &amp; 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™ Salmonella</p>
5	<p>Generic Name:Chip-based Real Time PCR Test for Hepatitis B Virus</p> <p>Model No.:NIL</p> <p>Intended Use:Truenat™ HBV is a chip-based Real Time Polymerase Chain Reaction (PCR) test for the quantitative estimation of the Hepatitis B Virus (HBV) in human blood /serum/ plasma specimen and aids in the diagnosis of infection with Hepatitis B Virus and in the estimation of viral load. Truenat™ HBV runs on the Truelab™ Real Time Quantitative micro PCR Analyzers.</p> <p>Class of medical device:Class C</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 Hepatitis B Virus and internal control DNA), dNTPs, DNA polymerase in proprietary buffer. 3. DNase &amp; 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™ HBV</p>

6	<p>Generic Name:Chip-based Real Time PCR Test for Rifampicin Resistant Mycobacterium tuberculosis</p> <p>Model No.:NIL</p> <p>Intended Use:Truenat™ MTB-RIF is a chip-based Real Time Polymerase Chain Reaction (PCR) test for the detection of Rifampicin resistance in Mycobacterium tuberculosis (MTB) in Truenat™ MTB/MTB Plus positive human specimen and aids in the diagnosis of MDR-TB. This test detects the presence of major mutations (SNPs) in the MTB genome that are known to cause resistance to rifampicin. Truenat™ MTB-RIF runs on the Truelab™ Uno Real Time micro PCR Analyzer. This is a follow on test, to be performed only on the extracted DNA from Truenat™ MTB/MTB Plus positive sample.</p> <p>Class of medical device:Class C</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 wild type rpoB gene of Mycobacterium tuberculosis and two mutation prone regions of rpoB gene, which is known marker for Rifampicin resistant phenotype), dNTPs, DNA polymerase in proprietary buffer. 3. DNase &amp; 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™ MTB-RIF</p>
7	<p>Generic Name:Chip-based Real Time PCR Test for Chlamydia trachomatis</p> <p>Model No.:NIL</p> <p>Intended Use:Truenat™ CT is a chip-based Real Time Polymerase Chain Reaction (PCR) test for the semiquantitative detection of Chlamydia trachomatis in female endocervical and vaginal swab specimens, male urethral swab specimen and male and female Urine specimen. It aids in the diagnosis of symptomatic or asymptomatic infection with Chlamydia trachomatis. Truenat™ CT runs on the Truelab™ Real Time micro Quantitative PCR Analyzers.</p> <p>Class of medical device:Class C</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 Chlamydia trachomatis bacteria and internal control DNA), dNTPs, DNA polymerase in proprietary buffer. 3. DNase &amp; 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™ CT</p>

8	<p>Generic Name:Chip-based Real Time PCR Test for Neisseria gonorrhoeae</p> <p>Model No.:NIL</p> <p>Intended Use:Truenat™ NG is a chip-based Real Time Polymerase Chain Reaction (PCR) test for the semiquantitative detection of Neisseria gonorrhoeae in female endocervical and vaginal swab specimens, male urethral swab specimens and male and female Urine specimen. It aids in the diagnosis of symptomatic or asymptomatic infection with Neisseria gonorrhoeae. Truenat™ NG runs on the Truelab™ Real Time Quantitative micro PCR Analyzers.</p> <p>Class of medical device:Class C</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 Neisseria gonorrhoeae bacteria and internal control DNA), dNTPs, DNA polymerase in proprietary buffer. 3. DNase &amp; 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™ NG</p>
9	<p>Generic Name:Chip-based Real Time PCR Test for Trichomonas vaginalis</p> <p>Model No.:NIL</p> <p>Intended Use:Truenat™ Trich is a chip-based Real Time Polymerase Chain Reaction (PCR) test for the semiquantitative detection of Trichomonas vaginalis in female endocervical and vaginal swab specimens, male urethral swab specimen and male and female Urine specimen. It aids in the diagnosis of symptomatic or asymptomatic infection with Trichomonas vaginalis. Truenat™ Trich runs on the Truelab™ Real Time Quantitative micro PCR Analyzers.</p> <p>Class of medical device:Class C</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 Trichomonas vaginalis protozoan parasite and internal control DNA), dNTPs, DNA polymerase in proprietary buffer. 3. DNase &amp; 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™ Trich</p>

10	<p>Generic Name:Chip-based Real Time Duplex PCR Test for Chlamydia trachomatis and Neisseria gonorrhoeae</p> <p>Model No.:NIL</p> <p>Intended Use:Truenat™ CT/NG is a chip-based Real Time Polymerase Chain Reaction (PCR) test for the semiquantitative detection of Chlamydia trachomatis and Neisseria gonorrhoeae in female endocervical and vaginal swab specimens, male urethral swab specimen, male and female Urine specimen. It aids in the diagnosis of symptomatic or asymptomatic infection with Chlamydia trachomatis and Neisseria gonorrhoeae. Truenat™ CT/NG runs on Truelab™ Real Time Quantitative micro PCR Analyzer.</p> <p>Class of medical device:Class C</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 Chlamydia trachomatis and Neisseria gonorrhoeae bacteria and internal control DNA), dNTPs, DNA polymerase in proprietary buffer. 3. DNase &amp; 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™ CT/NG</p>
1 1	<p>Generic Name:Chip-based Real Time PCR Test for Rifampicin Resistant Mycobacterium tuberculosis</p> <p>Model No.:NIL</p> <p>Intended Use:Truenat™ MTB-RIF Dx is a chip-based Real Time Polymerase Chain Reaction (PCR) test for the detection of Rifampicin resistance in Mycobacterium tuberculosis (MTB) in Truenat™ MTB/MTB Plus positive human specimen and aids in the diagnosis of MDR-TB. This test detects the presence of major mutations (SNPs) in the MTB genome that are known to cause resistance to rifampicin. Truenat™ MTB-RIF Dx runs on the Truelab™ Real Time Quantitative micro PCR Analyzer. This is a follow on test, to be performed only on the extracted DNA from Truenat™ MTB/MTB Plus positive sample.</p> <p>Class of medical device:Class C</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 wild type rpoB gene of Mycobacterium tuberculosis, which covers mutation prone regions of rpoB gene specific to rifampicin resistance and internal control DNA), dNTPs, DNA polymerase in proprietary buffer. 3. DNase &amp; 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™ MTB-RIF Dx</p>

12	<p>Generic Name:Chip-based Real Time PCR Test for Mycobacterium tuberculosis</p> <p>Model No.:NIL</p> <p>Intended Use:Truenat™ MTB Plus is a chip-based Real Time Polymerase Chain Reaction (PCR) test for the semiquantitative detection and diagnosis of Mycobacterium tuberculosis (MTB) in human pulmonary (sputum/non-sputum) and EPTB specimen and aids in the diagnosis of infection with MTB. Truenat™ MTB Plus runs on the Truelab™ Real Time micro Quantitative PCR analyzers.</p> <p>Class of medical device:Class C</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 ribonucleoside-diphosphate reductase gene and insertion sequence (IS6110) of Mycobacterium tuberculosis and internal control DNA), dNTPs, DNA polymerase in proprietary buffer. 3. DNase &amp; 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™ MTB Plus</p>
13	<p>Generic Name:Chip-based Real Time PCR Test for Dengue</p> <p>Model No.:NIL</p> <p>Intended Use:Truenat™ Dengue is a chip-based Real Time Reverse Transcription Polymerase Chain Reaction (RT PCR) test for the quantitative detection and diagnosis of Dengue virus in human blood/serum/plasma specimen and aids in the diagnosis of infection with Dengue. Truenat™ Dengue runs on the Truelab™ Real Time Quantitative micro PCR Analyzers.</p> <p>Class of medical device:Class C</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 Reverse Transcriptase, Oligonucleotides (primers and probes specific to Dengue and internal control DNA), dNTPs, DNA polymerase in proprietary buffer. 3. DNase &amp; 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™ Dengue</p>
14	<p>Generic Name:Chip-based Real Time PCR Test for Chikungunya</p> <p>Model No.:NIL</p> <p>Intended Use:Truenat™ Chikungunya is a chip-based Real Time Reverse Transcription Polymerase Chain Reaction (RT PCR) test for the quantitative detection and diagnosis of Chikungunya virus in human blood/serum/plasma specimen and aids in the diagnosis of infection with Chikungunya. Truenat™ Chikungunya runs on the Truelab™ Real Time Quantitative micro PCR Analyzers.</p> <p>Class of medical device:Class C</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 Reverse Transcriptase, Oligonucleotides (primers and probes specific to Chikungunya and internal control DNA), dNTPs, DNA polymerase in proprietary buffer. 3. DNase &amp; 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™ Chikungunya</p>

15	<p>Generic Name:Chip-based Real Time Duplex PCR Test for Dengue and Chikungunya</p> <p>Model No.:NIL</p> <p>Intended Use:Truenat™ Dengue/Chikungunya is a chip-based Real Time Reverse Transcription Polymerase Chain Reaction (RT PCR) test for the quantitative detection of Dengue and Chikungunya virus in human blood/serum/plasma specimen and aids in the differential diagnosis of infection with Dengue and/or Chikungunya virus. Truenat™ Dengue/Chikungunya runs on the Truelab™ Real Time Quantitative micro PCR Analyzer.</p> <p>Class of medical device:Class C</p> <p>Material of construction:A. Individually sealed pouches, each containing: 1. Micro PCR chip pre-loaded with dried down proprietary buffer and sealed with inert polymer. 2. Microtube containing freeze dried biomix comprising Reverse Transcriptase, Oligonucleotides (primers and probes specific to Dengue and Chikungunya and internal control DNA), dNTPs, DNA polymerase in proprietary buffer. 3. DNase &amp; 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™ Dengue/Chikungunya</p>
16	<p>Generic Name:Chip-based Real Time PCR Test for H1N1</p> <p>Model No.:NIL</p> <p>Intended Use:Truenat™ H1N1 is a chip-based Real Time Reverse Transcription Polymerase Chain Reaction (RT PCR) test for the semiquantitative detection of H1N1 virus in human throat and nasal swab specimen and aids in the diagnosis of infection with H1N1. Truenat™ H1N1 runs on Truelab™ Real Time micro Quantitative PCR Analyzers.</p> <p>Class of medical device:Class C</p> <p>Material of construction:A. Individually sealed pouches, each containing: 1. Micro PCR chip pre-loaded with dried down proprietary buffer and sealed with inert polymer. 2. Microtube containing freeze dried biomix comprising Reverse Transcriptase, Oligonucleotides (primers and probes specific to H1N1 and RNase P as internal positive control for human nucleic acid), dNTPs, DNA polymerase in proprietary buffer. 3. DNase &amp; 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™ H1N1</p>



17	<p>Generic Name:Chip-based Real Time PCR Test for Rabies Virus</p> <p>Model No.:NIL</p> <p>Intended Use:Truenat™ Rabies is a chip-based Real Time Reverse Transcription Polymerase Chain Reaction (RT PCR) test for the semiquantitative detection of Rabies virus in Cerebrospinal fluid (CSF), saliva, brain tissue, corneal swabs specimens of animals and aids in the diagnosis of infection with Rabies virus. Truenat™ Rabies runs on the Truelab™ Real Time micro Quantitative PCR Analyzers.</p> <p>Class of medical device:Class C</p> <p>Material of construction:A. Individually sealed pouches, each containing: 1. Micro PCR chip pre-loaded with dried down proprietary buffer and sealed with inert polymer. 2. Microtube containing freeze dried biomix comprising Reverse Transcriptase, Oligonucleotides (primers and probes specific to Rabies and internal control DNA), dNTPs, DNA polymerase in proprietary buffer. 3. DNase &amp; 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™ Rabies</p>
18	<p>Generic Name:Chip-based Real Time Duplex PCR Test for Human Papillomavirus High Risk Types 16, 31 and 18, 45</p> <p>Model No.:NIL</p> <p>Intended Use:Truenat™ HPV-HR is a chip-based Real Time Polymerase Chain Reaction (PCR) test for the semiquantitative detection of high risk Human Papillomavirus (HPV) types 16, 18, 31 and 45 in female cervical specimens collected by a clinician. It aids in the differential diagnosis of symptomatic or asymptomatic infection with high risk HPV types 16, 31 and 18, 45. Truenat™ HPV-HR runs on the Truelab™ Real Time Quantitative micro PCR Analyzer.</p> <p>Class of medical device:Class C</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 HPV types 16,18,31 &amp; 45 and internal control DNA), dNTPs, DNA polymerase in proprietary buffer. 3. DNase &amp; 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™ HPV- HR</p>

19	<p>Generic Name:Chip-based Real Time Duplex PCR Test for Influenza A and Influenza B Virus Model No.:NIL</p> <p>Intended Use:Truenat™ Influenza A/B is a Chip-based Real Time Reverse Transcription Polymerase Chain Reaction (RT-PCR) test for the semi quantitative detection of Influenza A and Influenza B virus in human throat and nasal swab specimen and aids in differential diagnosis of infection with Influenza A and/or Influenza B virus. Truenat™ Influenza A/B runs on the Truelab™ Real Time Quantitative micro PCR Analyzer.</p> <p>Class of medical device:Class C</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 Reverse Transcriptase, Oligonucleotides (primers and probes specific to Influenza A and Influenza B and internal control DNA), dNTPs, DNA polymerase in proprietary buffer. 3. DNase &amp; 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™ Influenza A/B</p>
20	<p>Generic Name:Chip-based Real Time PCR Test for Group B Streptococcus Model No.:NIL</p> <p>Intended Use:Truenat™ GBS is a chip-based Real Time Polymerase Chain Reaction (PCR) test for the semi quantitative detection and diagnosis of Group B Streptococcus in vagino-rectal swab specimen and aids in the diagnosis of infection with Group B Streptococcus. Truenat™ GBS runs on the Truelab™ Real Time Quantitative micro PCR Analyzers.</p> <p>Class of medical device:Class C</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 Group B Streptococcus and internal control DNA), dNTPs, DNA polymerase in proprietary buffer. 3. DNase &amp; 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™ GBS</p>
21	<p>Generic Name:Chip-based Real Time PCR Test for Haemophilus influenzae type B Model No.:NIL</p> <p>Intended Use:Truenat™ HIB is a chip-based Real Time Polymerase Chain Reaction (PCR) test for the semi quantitative detection of Haemophilus influenzae type B in blood/ serum/ plasma, cerebrospinal fluid (CSF) and swabs specimens. It aids in the diagnosis of infections with Haemophilus influenzae type B. Truenat™ HIB runs on the Truelab™ Real Time Quantitative micro PCR Analyzers.</p> <p>Class of medical device:Class C</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 Haemophilus influenzae type B and internal control DNA), dNTPs, DNA polymerase in proprietary buffer. 3. DNase &amp; 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™ HIB</p>

22	<p>Generic Name:Chip-based Real Time PCR Test for Neisseria meningitidis</p> <p>Model No.:NIL</p> <p>Intended Use:Truenat™ Nm is a chip-based Real Time Polymerase Chain Reaction (PCR) test for the quantitative detection of Neisseria meningitidis in blood and cerebrospinal fluid (CSF) specimens. It aids in the diagnosis of infections with Neisseria meningitidis. Truenat™ Nm runs on the Truelab™ Real Time Quantitative micro PCR Analyzers.</p> <p>Class of medical device:Class C</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 Neisseria meningitidis and internal control DNA), dNTPs, DNA polymerase in proprietary buffer. 3. DNase &amp; 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™ Nm</p>
23	<p>Generic Name:Chip-based Real Time PCR Test for Streptococcus pneumoniae</p> <p>Model No.:NIL</p> <p>Intended Use:Truenat™ S.pneumoniae is a chip-based Real Time Polymerase Chain Reaction (PCR) test for the semi quantitative detection of Streptococcus pneumoniae in blood/ serum/ plasma, cerebrospinal fluid (CSF) and swabs specimens. It aids in the diagnosis of infections with Streptococcus pneumoniae. Truenat™ S.pneumoniae runs on the Truelab™ Real Time Quantitative micro PCR Analyzers.</p> <p>Class of medical device:Class C</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 Streptococcus pneumoniae and internal control DNA), dNTPs, DNA polymerase in proprietary buffer. 3. DNase &amp; 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™ S. pneumoniae</p>

24	<p>Generic Name:Chip-based Real Time Duplex PCR Test for <i>Neisseria meningitides</i> and <i>Streptococcus pneumoniae</i></p> <p>Model No.:NIL</p> <p>Intended Use:Truenat™ Nm/S.pneumoniae is a chip-based Real Time Polymerase Chain Reaction (PCR) test for the quantitative detection of <i>Neisseria meningitides</i> and <i>Streptococcus pneumoniae</i> in blood/serum/plasma and cerebrospinal fluid (CSF) specimens. It aids in the differential diagnosis of infections with <i>Neisseria meningitides</i> and/or <i>Streptococcus pneumoniae</i>. Truenat™ Nm/S. pneumoniae runs on the Truelab™ Real Time Quantitative micro PCR Analyzers.</p> <p>Class of medical device:Class C</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 <i>Neisseria meningitides</i> and <i>Streptococcus pneumoniae</i> and internal control DNA), dNTPs, DNA polymerase in proprietary buffer. 3. DNase &amp; 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™ Nm/S.pneumoniae</p>
25	<p>Generic Name:Chip – based Real Time Duplex PCR Test for <i>Staphylococcus aureus</i> and <i>Pseudomonas aeruginosa</i></p> <p>Model No.:NIL</p> <p>Intended Use:Truenat™ Staph/PA is a chip-based Real Time Polymerase Chain Reaction (PCR) test for the semi quantitative detection of <i>Staphylococcus aureus</i> and <i>Pseudomonas aeruginosa</i> in blood/ serum/ plasma and swabs specimens. It aids in the differential diagnosis of infections with <i>Staphylococcus aureus</i> and/or <i>Pseudomonas aeruginosa</i>. Truenat™ Staph/PA runs on the Truelab™ Real Time Quantitative micro PCR Analyzers.</p> <p>Class of medical device:Class C</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 <i>Staphylococcus aureus</i> and <i>Pseudomonas aeruginosa</i> and internal control DNA), dNTPs, DNA polymerase in proprietary buffer. 3. DNase &amp; 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™ Staph/PA</p>

26	<p>Generic Name:Chip-based Real Time PCR Test for Hepatitis A Virus</p> <p>Model No.:NIL</p> <p>Intended Use:Truenat™ HAV is a chip-based Real Time Reverse Transcription Polymerase Chain Reaction (RT PCR) test for the quantitative detection and diagnosis of Hepatitis A virus in human blood /serum/ plasma specimen and aids in the diagnosis of infection with Hepatitis A Virus. Truenat™ HAV runs on the Truelab™ Real Time Quantitative micro PCR Analyzers.</p> <p>Class of medical device:Class C</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 Reverse Transcriptase, Oligonucleotides (primers and probes specific to Hepatitis A Virus and internal control DNA), dNTPs, DNA polymerase in proprietary buffer. 3. DNase &amp; 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™ HAV</p>
27	<p>Generic Name:Chip-based Real Time PCR Test for Hepatitis E Virus</p> <p>Model No.:NIL</p> <p>Intended Use:Truenat™ HEV is a chip-based Real Time Reverse Transcription Polymerase Chain Reaction (RT PCR) test for the quantitative detection of Hepatitis E Virus in blood/ serum/ plasma and aids in monitoring of HEV viral load of patients with HEV infection. Truenat™ HEV runs on the Truelab™ Real Time Quantitative micro PCR Analyzers.</p> <p>Class of medical device:Class C</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 Reverse Transcriptase, Oligonucleotides (primers and probes specific to Hepatitis E Virus and internal control DNA), dNTPs, DNA polymerase in proprietary buffer. 3. DNase &amp; 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™ HEV</p>
28	<p>Generic Name:Chip-based Real Time PCR Test for Pseudomonas aeruginosa</p> <p>Model No.:NIL</p> <p>Intended Use:Truenat™ PA is a chip-based Real Time Polymerase Chain Reaction (PCR) test for the semi quantitative detection of Pseudomonas aeruginosa in blood/ serum/ plasma and swabs specimens. It aids in the diagnosis of infections with Pseudomonas aeruginosa. Truenat™ PA runs on the Truelab™ Real Time Quantitative micro PCR Analyzers.</p> <p>Class of medical device:Class C</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 Pseudomonas aeruginosa and internal control DNA), dNTPs, DNA polymerase in proprietary buffer. 3. DNase &amp; 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™ PA</p>

Place:

Date:12-Jun-19

Central Licensing Authority

