



EU Declaration of Conformity

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| Name of Device / Product Group | Identification (DD, ID, MB, TD, CT) |
| Product Description | Products for the identification of microorganisms or detection of bacterial toxins |
| Product Code / Product and Trade Name | See Attached Product List |
|  Legal Manufacturer | Oxoid Limited, Wade Road, Basingstoke, Hampshire, RG24 8PW, United Kingdom |
|  European Authorized Representative | Thermo Fisher Diagnostics B.V. Scheepsbouwersweg 1 B, 1121 PC Landsmeer, The Netherlands |
| Risk Class | Self-Declared – Non-Annex II Products and Not Self-Test Devices |
| Conformity Route | Annex III |

We, as the legal manufacturer of the device(s) take sole responsibility for and hereby declare that the listed product(s) meet the provisions of EC Directive 98/79/EC concerning In Vitro Diagnostic Medical Devices (IVDD).

This declaration is supported by the Quality Management System which is certified to EN ISO 13485:2016 Standard (BSI Certificate no. MD 80930).

Signature:

Name:

Function: Regulatory Affairs

Issued in: United Kingdom

Product Schedule

The products related to EU Declaration of Conformity - Identification (DD ID MD TD CT) Rev 4 are listed below:

| Product Code | Product and Trade Name | Basic UDI | GMDN Code |
|--------------|--|---------------|-----------|
| DD0001B | OPTOCHIN | 5032384104642 | 36085 |
| DD0001T | OPTOCHIN | 5032384033911 | 36085 |
| DD0002B | BACITRACIN (BC DD) | 5032384107759 | 43680 |
| DD0002T | BACITRACIN (BC DD) | 5032384034031 | 43680 |
| DD0003B | X FACTOR | 5032384104635 | 43513 |
| DD0003T | X FACTOR | 5032384034055 | 43513 |
| DD0004B | V FACTOR | 5032384104659 | 30655 |
| DD0004T | V FACTOR | 5032384034079 | 30655 |
| DD0005B | X & V FACTOR | 5032384105014 | 43678 |
| DD0005T | X & V FACTOR | 5032384034109 | 43678 |
| DD0006A | AN-IDENT DISCS DD6 6X50 DISCS | 5032384007189 | 45367 |
| DD0008T | SINGLE CARTRIDGE METRONIDAZOLE 50 DD8 | 5032384034130 | 35665 |
| DD0011T | SUL SULPHONAMIDE | 5032384034147 | 41200 |
| DD0013T | SINGLE CARTRIDGE ONPG DISCS DD13 | 5032384034154 | 34176 |
| DD0015T | SINGLE CARTRIDGE O129 DISCS (150Ág) DD15 | 5032384034178 | 43683 |
| DD0016T | SINGLE CARTRIDGE SPS DISCS DD16 | 5032384034185 | 43602 |
| DD0024S | B0.2 BACITRACIN SINGLE | 5032384118069 | 63834 |
| DD0026B | CEFOXITIN 10 | 5032384125265 | 42723 |
| DD0027B | KANAMYCIN K1000 | 5032384134014 | 63834 |
| DD0028B | FURAZOLIDONE 100Ág | 5032384177349 | 35648 |
| DD0029B | CEFPODOXIME COMBI DISC KIT (CPD10/CD01) | 5032384186938 | 42733 |
| CT1106S | DA15 CLINDAMYCIN | 5032384008384 | 63834 |
| CT1152S | OL50 OLEANDOMYCIN | 5032384008834 | 63834 |
| CT1163S | MTZ10 METRONIDAZOLE | 5032384008940 | 63834 |
| ID0570M | OBIS SALMONELLA 60 TESTS | 5032384075423 | 65107 |
| ID0580M | OBIS - PYR 60 TEST KITS | 5032384060344 | 63421 |
| ID0600M | OBIS MONO KIT | 5032384122127 | 51113 |
| ID0800M | O.B.I.S CAMPY KIT | 5032384167746 | 50683 |
| MB0180A | MICROBACT REAGENT TDA | 5032384127504 | 61331 |
| MB0181A | MICROBACT REAGENT VP I | 5032384127818 | 61331 |

| Product Code | Product and Trade Name | Basic UDI | GMDN Code |
|--------------|---|---------------|-----------|
| MB0184A | MICROBACT REAGENT VP II | 5032384127825 | 61331 |
| MB0186A | MICROBACT REAGENT NITRATE A | 5032384127832 | 61331 |
| MB0187A | MICROBACT REAGENT NITRATE B | 5032384127849 | 61331 |
| MB0209A | MICROBACT REAGENT INDOLE - KOVACS | 5032384127856 | 61331 |
| MB0266A | OXIDASE STRIPS | 5032384127863 | 61331 |
| MB0266B | OXIDASE STRIPS | 5032384514359 | 61331 |
| MB1082A | MICROBACT REAGENT SET D | 5032384127917 | 61331 |
| MB1093A | MICROBACT MINERAL OIL | 5032384127924 | 61331 |
| MB1128A | MICROBACT LISTERIA 12L (20 ID'S) | 5032384127498 | 61331 |
| MB1131A | MICROBACT GNB 24E TRAY (40 ID'S) | 5032384127955 | 61331 |
| MB1132A | MICROBACT GNB 12A STRIP (60 ID'S) | 5032384127962 | 61331 |
| MB1133A | MICROBACT GNB 12B STRIP (60 ID'S) | 5032384127979 | 61331 |
| MB1244A | MICROBACT PROGRAM FOR WINDOWS | 5032384127986 | 61331 |
| MB1249A | MICROBACT LISTERIA 12L HAEMOLYSIN REAGENT | 5032384187553 | 61331 |
| MB1448A | REAGENT SPOT INDOLE DMACA | 5032384127993 | 61331 |
| MB1561A | MICROBACT STAPH 12S | 5032384128006 | 61331 |
| MB1588A | MICROBACT STAPH FAST BLUE REAGENT | 5032384128013 | 61331 |
| TD0900A | SET RPLA KIT | 5032384029587 | 51680 |
| TD0920A | VET-RPLA KIT | 5032384028511 | 51671 |
| TD0930A | PET RPLA KIT | 5032384028528 | 50857 |
| TD0940A | TST RPLA | 5032384029594 | 51671 |
| TD0950A | BCET RPLA KIT | 5032384028535 | 50440 |
| TD0960A | VTEC RPLA KIT | 5032384028542 | 50913 |