



EU Declaration of Conformity

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