


EU Declaration of Conformity

Name of Device / Product Group	Culture Media (BO, EB, PB, PO, TV)
Product Description	Culture media for the growth, maintenance and/or processing of microorganisms.
Product Code / Product and Trade Name	See attached product schedule
 Legal Manufacturer	Oxoid Deutschland GmbH Am Lippegelacis 4-8, 46483 Wesel, DE SRN: DE-MF-000025401
EC REP European Authorized Representative	Thermo Fisher Diagnostics B.V. Scheepsbouwersweg 1 B, 1121 PC Landsmeer, The Netherlands
Risk Class	Class A in accordance with the rules set out in Annex VIII of Regulation (EU) 2017/746 (IVDR)
Conformity Assessment Procedure Performed	Self-declared in accordance with Articles 17 and 48(10) of Regulation (EU) 2017/746 (IVDR)
Certificate(s) Issued	EN ISO 13485:2016 – MD 741787

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 the following regulation:

- Regulation (EU) 2017/746 on In Vitro Diagnostic Medical Devices (IVDR)

This declaration is supported by the Quality Management System which is certified to EN ISO 13485:2016 Standard (BSI Certificate no. MD 741787).

Signature:



Name:

Peter E. Shearstone

Function:

Regulatory Affairs

Issued in:

United Kingdom

Product Schedule

The products related to MBD EU IVDR Declaration of Conformity - Culture Media (BO, EB, PB, PO, TV) Class A (Rev 8) are listed below:

Product Code	Product and Trade Name	UDI	GMDN Code
PB5006A	BUTZLER SELECTIVE MEDIUM	5032384128327	58537
PB5007A	MUELLER-HINTON AGAR WITH SHEEP BLOOD	5032384128341	58639
PB5008A	COLUMBIA AGAR WITH SHEEP BLOOD	5032384128358	58688
PB5012A	TRYPTONE SOYA AGAR WITH SHEEP BLOOD	5032384128365	58688
PB5034A	SCHAEDLER AGAR WITH SHEEP BLOOD +HAEMIN +VITAMIN K	5032384128389	58688
PB5039A	COLUMBIA AGAR WITH SHEEP BLOOD PLUS	5032384128402	58688
PB5049A	STAPH/STREP SELECTIVE MEDIUM	5032384128419	58585
PB5065A	BORDETELLA SELECTIVE MEDIUM	5032384128440	58585
PB5067A	GARDNERELLA VAGINALIS SELECTIVE MEDIUM	5032384128457	58585
PB5082A	COLUMBIA CAP SELECTIVE AGAR WITH SHEEP BLOOD	5032384128471	58688
PB5105A	ENTEROHEMOLYSIN AGAR WITH BLOOD	5032384128532	58688
PB5115A	COLUMBIA CNA AESCULIN SELECTIVE AGAR	5032384128587	58585
PB5166A	AZTREONAM SELECTIVE AGAR WITH SHEEP BLOOD	5032384128648	58688
PB5186A	7% SHEEP BLOOD AGAR WITH GENTAMICIN	5032384167012	58688
PB5202E	COLUMBIA AGAR WITH BLOOD / CHOCOLATE AGAR	5032384128662	62106
PB5204E	SCHAEDLER AGAR / SCHAEDELER KV SELECTIVE AGAR	5032384128679	62106
PB5207E	COLUMBIA AGAR WITH BLOOD / MACCONKEY AGAR NO. 3	5032384128686	62106
PB5224E	COLUMBIA CNA AESCULIN AGAR / MACCONKEY NO. 3, MOD.	5032384128716	62106
PB5250E	COLUMBIA AGAR+SB PLUS/SCHOKO-AGAR+SB	5032384277018	62106
PB5253E	COLUMBIA SHEEPBLOOD PLUS/ BRILLIANCE MRSA 2 AGAR	5032384295050	58688
PB5267E	COLUMBIA CNA AGAR / BRILLIANCE UTI CLARITY	5032384528011	62106
PB5303A	MUELLER HINTON WITH HORSE BLOOD	5032384189168	58639
PB5306A	SHEEP BLOOD AGAR	5032384228539	58688

Product Code	Product and Trade Name	UDI	GMDN Code
PO5001A	SABOURAUD-GLUCOSE-AGAR	5032384127795	58585
PO5002A	MACCONKEY AGAR NO. 3	5032384128785	58585
PO5004A	NEISSERIA SELECTIVE MEDIUM PLUS	5032384128792	58585
PO5007A	MUELLER-HINTON AGAR	5032384128815	58639
PO5009A	C.L.E.D. MEDIUM	5032384126996	58585

Product Code	Product and Trade Name	UDI	GMDN Code
PO5012A	TRYPTONE SOYA AGAR	5032384128846	58688
PO5016A	DESOXYCHOLATE-CITRATE AGAR (HYNES)	5032384128891	58585
PO5019A	KIMMIG MEDIUM	5032384128921	58585
PO5020A	SCHAEDLER KV AGAR+LYSED HORSE BLOOD+HAEMIN+VIT.K	5032384128938	58688
PO5021A	GASSNER MEDIUM	5032384128945	58585
PO5022A	S.S. AGAR	5032384128952	58585
PO5027A	MANNITOL SALT AGAR	5032384129010	58585
PO5028A	LEGIONELLA BCYEA MEDIUM WITHOUT CYSTEIN	5032384129027	58585
PO5029A	MLCB AGAR	5032384129034	58585
PO5033A	BRILLIANT GREEN AGAR (MODIFIED)	5032384129065	58585
PO5035A	LEGIONELLA BMPA SELECTIVE MEDIUM	5032384129072	58585
PO5037A	DERMASEL SELECTIVE MEDIUM	5032384129096	58585
PO5040A	SKIRROW SELECTIVE MEDIUM	5032384129102	58585
PO5041A	KARMALI SELECTIVE MEDIUM	5032384129119	58585
PO5044A	YERSINIA SELECTIVE MEDIUM (CIN)	5032384129140	58585
PO5045A	EMB AGAR (LEVINE)	5032384129157	58585
PO5047A	M.R.S. AGAR	5032384129164	58585
PO5048A	BAC. CEREUS-SELEKTIV MEDIUM (PEMBA)	5032384129171	58585
PO5050A	TRYPTONE SOYA YEAST EXTRACT AGAR (TSYEA)	5032384129188	58585
PO5057A	X.L.D. MEDIUM	5032384129225	58585
PO5062A	ENTEROCOCCUS SELECTIVE AGAR (BAA)	5032384129256	58585
PO5069A	SORBITOL MACCONKEY AGAR	5032384129300	58585
PO5070A	SABOURAUD GLUCOSE CHLORAMPHENICOL SEL. AGAR	5032384129317	58585
PO5072A	LEGIONELLA BCYE MEDIUM	5032384129331	58685
PO5076A	CETRIMIDE AGAR	5032384129379	58585
PO5081A	MYCOPLASMA / UREAPLASMA AGAR	5032384142026	58585
PO5086A	SABOURAUD GLUCOSE YEAST EXTRACT SELECTIVE AGAR	5032384154081	58585
PO5087A	DERMATOPHYTES SELECTIVE AGAR (TAPLIN)	5032384129430	58585
PO5090A	CHOCOLATE AGAR WITH VITOX	5032384129454	58688
PO5091A	CCDA SELECTIVE MEDIUM	5032384126965	58585
PO5096A	SABOURAUD GLUCOSE AGAR+GENTAMICIN+CHLORAMPH.	5032384129508	58585
PO5097A	HAEMOPHILUS SELECTIVE AGAR	5032384129515	58611
PO5098A	BRILLIANCE (TM) SALMONELLA	5032384156610	58585
PO5100A	HEKTOEN ENTERIC AGAR	5032384129522	58585

Product Code	Product and Trade Name	UDI	GMDN Code
PB5101A	YEAST EXTRACT CYSTEINE MEDIUM WITH SHEEP BLOOD	5032384128525	58688
PO5116A	XLT4 AGAR	5032384129607	58585
PO5118A	BCP AGAR	5032384129621	58585
PO5122A	DRIGALSKI-LACTOSE-AGAR	5032384129669	58585
PO5131A	MACCONKEY AGAR WITHOUT SODIUM CHLORIDE	5032384126972	58585
PO5132A	PSEUDOMONAS CFC SELECTIVE AGAR	5032384129713	58585
PO5138A	HAEMOPHILUS TEST MEDIUM (HTM)	5032384129768	58611
PO5139A	MUELLER-HINTON AGAR WITH 2% SODIUM CHLORIDE	5032384129775	58639
PO5140A	MACCONKEY AGAR NO.3, MOD.	5032384129782	58585
PO5146A	MACCONKEY AGAR	5032384129836	58585
PO5159A	BRILLIANCE (TM) UTI CLARITY (TM)	5032384165032	58585
PO5167A	DRIGALSKI-LACTOSE AGAR	5032384130009	58585
PO5169A	CHROMOGENIC C. ALBICANS AGAR	5032384130023	58585
PO5185A	GCG AGAR (BILE CHRYSOIDIN GLYCEROL AGAR) WITH MUG	5032384170715	58585
PO5210E	S.S. AGAR / X.L.D. MEDIUM	5032384130085	62106
PO5217E	C.L.E.D. MEDIUM / MACCONKEY AGAR NO. 3	5032384130122	62106
PO5219E	KARMALI SELECTIVE MEDIUM / KARMALI SELECTIVE MEDIUM	5032384130139	62106
PO5222E	YERSINIA-SEL.-NB (CIN)/YERSINIA-SEL.-NB (CIN)	5032384130146	62106
PO5243E	SABOURAUD DEXTROSE GC/CHROMOGENIC C. ALBICANS AGAR	5032384131150	62106
PO5248E	XLD AGAR / BRILLIANCE SALMONELLA	5032384166510	62106
PB5254E	COLUMBIA AGAR WITH SHEEP BLOOD PLUS/ MACCONKEY AGAR W/O SALT	5032384295814	62106
PO5257E	HEKTOEN ENTERIC AGAR/DCA (LEIFSON)	5032384445998	58585
PO5302A	BRILLIANCE (TM) ESBL AGAR	5032384181414	58585
PO5310A	BRILLIANCE (TM) MRSA 2 AGAR	5032384275670	58585
PO5312A	MRS AGAR WITH HRP	5032384280490	58585
PO5320A	BRILLIANCE TM GBS AGAR	5032384448012	58585
PO5403I	MUELLER-HINTON-AGAR	5032384508822	58639

Product Code	Product and Trade Name	UDI	GMDN Code
TV5001D	THIOGLYCOLAT-MEDIUM U.S.P. (50X9ML)	5032384128334	58687
TV5002E	TRYPTONE SOYA BROTH USP	5032384130276	58687
TV5003D	NUTRIENT BROTH WITH GLUCOSE	5032384130283	58586

Product Code	Product and Trade Name	UDI	GMDN Code
TV5004D	KLIGER IRON SLANT AGAR (WITH UREA)	5032384130290	58585
TV5005I	SELENITE LACTOSE BROTH	5032384130306	58684
TV5006I	TETRATHIONATE BROTH (MULLER-KAUFFMANN)	5032384131068	58684
TV5007N	UREA BROTH (CHRISTENSEN & MASLEN)	5032384130313	58684
TV5008D	SCHAEDLER BROTH (WITH HEMINE AND VITAMIN K)	5032384130320	58687
TV5011Z	NUTRIENT SLANT AGAR	5032384130351	58685
TV5016D	MAXIMUM RECOVERY DILUENT	5032384130399	58208
TV5018E	SELENITE CYSTINE BROTH	5032384130429	58684
TV5051I	TRYPTONE SOYA SLANT AGAR	5032384130733	58685
TV5056I	SABOURAUD GLUCOSE CHLORAMPHENICOL AGAR SLANT	5032384130788	58585
TV5057I	SABOURAUD GLUCOSE CG AGAR SLANT	5032384130795	58585
TV5058I	SABOURAUD GLUCOSE CGC AGAR SLANT	5032384130801	58585
TV5059D	SCHAEDLER BROTH WITH 0,2% AGAR	5032384130825	58684
TV5060D	SCHAEDLER BROTH WITH 0,02% AGAR	5032384130818	58684
TV5074D	TRIPLE SUGAR IRON SLANT AGAR	5032384130917	58585
TV5081A	MYCOPLASMA/ UREAPLASMA ENRICHMENT BROTH	5032384142033	58684
TV5090E	BRAIN HEART INFUSION BROTH	5032384229765	58687
TV5093E	TODD HEWITT WITH CNA (LIM)	5032384478835	58684
TV5095D	THIOGLYCOLAT-MEDIUM +HEMINE&VITAMINE (50x9ML)	5032384512638	58684

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