



## EU Declaration of Conformity

Name of Device / Product Group	<b>Susceptibility (CT, ST)</b>
Product Description	Test discs and dispensers for antibiotic susceptibility testing of microorganisms.
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 - Suseptibility (CT ST) Rev 5 are listed below:

Product Code	Product and Trade Name	Basic UDI	GMDN Code
CT0002B	AMP2 AMPICILLIN	5032384005307	63834
CT0003B	AMP10 AMPICILLIN	5032384005505	63834
CT0004B	AMP25 AMPICILLIN	5032384005512	63834
CT0005B	B10 BACITRACIN	5032384005529	63834
CT0007B	CL30 CEPHALEXIN	5032384005543	63834
CT0010B	KF30 CEPHALOTHIN	5032384005550	63834
CT0011B	KZ30 CEPHAZOLIN	5032384005567	63834
CT0012B	C10 CHLORAMPHENICOL	5032384005574	63834
CT0013B	C30 CHLORAMPHENICOL	5032384005581	63834
CT0014B	C50 CHLORAMPHENICOL	5032384005598	63834
CT0015B	DA10 CLINDAMYCIN	5032384005604	63834
CT0017B	CT10 COLISTIN SULPHATE	5032384005628	63834
CT0018B	DO30 DOXYCYCLINE	5032384005635	63834
CT0019B	E10 ERYTHROMYCIN	5032384005642	63834
CT0020B	E15 ERYTHROMYCIN	5032384005659	63834
CT0021B	E30 ERYTHROMYCIN	5032384005666	63834
CT0023B	FD10 FUSIDIC ACID	5032384005680	63834
CT0024B	CN10 GENTAMICIN	5032384005697	63834
CT0025B	K5 KANAMYCIN	5032384005703	63834
CT0026B	K30 KANAMYCIN	5032384005710	63834
CT0027B	MY2 LINCOMYCIN	5032384005727	63834
CT0028B	MY15 LINCOMYCIN	5032384005734	63834
CT0030B	MH30 MINOCYCLINE	5032384005758	63834
CT0031B	NA30 NALIDIXIC ACID	5032384005765	63834
CT0032B	N10 NEOMYCIN	5032384005772	63834
CT0033B	N30 NEOMYCIN	5032384005789	63834
CT0034B	F100 NITROFURANTOIN	5032384005796	63834
CT0035B	F200 NITROFURANTOIN	5032384005802	63834
CT0036B	F300 NITROFURANTOIN	5032384005819	63834
CT0037B	NV5 NOVOBIOCIN	5032384005826	63834

Product Code	Product and Trade Name	Basic UDI	GMDN Code
CT0038B	NV30 NOVOBIOCIN	5032384005833	63834
CT0039B	OL15 OLEANDOMYCIN	5032384005840	63834
CT0040B	OX5 OXACILLIN	5032384005857	63834
CT0042B	P1.5 PENICILLIN G	5032384005871	63834
CT0043B	P10 PENICILLIN G	5032384005888	63834
CT0044B	PB300 POLYMYXIN B	5032384005895	63834
CT0047B	S10 STREPTOMYCIN	5032384005925	63834
CT0048B	S25 STREPTOMYCIN	5032384005932	63834
CT0051B	RL25 SULPHAMETHOXAZOLE	5032384005963	63834
CT0052B	SXT25 SULPHAMET/TRIMETHOP	5032384005970	63869
CT0053B	TE10 TETRACYCLINE	5032384005987	63834
CT0054B	TE30 TETRACYCLINE	5032384005994	63834
CT0056B	TOB10 TOBRAMYCIN	5032384006014	63834
CT0057B	W1.25 TRIMETHOPRIM	5032384006021	63834
CT0058B	VA30 VANCOMYCIN	5032384006038	63834
CT0059B	S3 300 COMPOUND SULPHONAMIDE	5032384006045	63834
CT0060B	AML2 AMOXYCILLIN	5032384006052	63834
CT0061B	AML25 AMOXYCILLIN	5032384006069	63834
CT0063B	CE30 CEPHRADINE	5032384006083	63834
CT0064B	DA2 CLINDAMYCIN	5032384006090	63834
CT0066B	E5 ERYTHROMYCIN	5032384006113	63834
CT0067B	MTZ5 METRONIDAZOLE	5032384006120	63834
CT0069B	F50 NITROFURANTOIN	5032384006137	63834
CT0071B	FY100 FRAMYCETIN	5032384006151	63834
CT0072B	CN30 GENTAMICIN	5032384006168	63834
CT0073B	NS100 NYSTATIN	5032384006175	63834
CT0074B	RL100 SULPHAMETHOXAZOLE	5032384006182	63834
CT0075B	SF300 SULPHAFURAZOLE	5032384006199	63834
CT0076B	W5 TRIMETHOPRIM	5032384006205	63834
CT0078B	RD2 RIFAMPICIN	5032384006229	63836
CT0088B	P2 PENICILLIN G	5032384006236	63834
CT0091B	MEL25 MECILLINAM	5032384006250	63834
CT0096B	MEL10 MECILLINAM	5032384006267	63834

Product Code	Product and Trade Name	Basic UDI	GMDN Code
CT0104B	RD30 RIFAMPICIN	5032384006274	63836
CT0107B	AK30 AMIKACIN	5032384006281	63834
CT0108B	MA30 CEFAMANDOLE	5032384006298	63834
CT0119B	FOX30 CEFOXITIN	5032384006304	63834
CT0123B	MY10 LINCOMYCIN	5032384006328	63834
CT0124B	P5 PENICILLIN G	5032384006335	63834
CT0127B	CXM30 CEFUROXIME	5032384006342	63834
CT0149B	CEC30 CEFACLOX	5032384006359	63834
CT0152B	P1 PENICILLIN G	5032384006366	63834
CT0159B	OX1 OXACILLIN	5032384006373	63834
CT0161B	AML10 AMOXYCILLIN	5032384006380	63834
CT0166B	CTX30 CEFOTAXIME	5032384006403	63834
CT0167B	TIC75 TICARCILLIN	5032384006410	63834
CT0174B	MEZ30 MEZLOCILLIN	5032384006427	63834
CT0180B	PIP20 PIPEMIDIC ACID	5032384006434	63834
CT0181B	OA2 OXOLINIC ACID	5032384006441	63834
CT0183B	FOS50 FOSFOMYCIN	5032384006458	63834
CT0188B	VA5 VANCOMYCIN	5032384006465	63834
CT0192B	MEZ75 MEZLOCILLIN	5032384006472	63834
CT0193B	CFP30 CEFOPERAZONE	5032384006489	63834
CT0199B	PRL100 PIPERACILLIN	5032384006502	63834
CT0207B	RD5 RIFAMPICIN	5032384006526	63836
CT0223B	AMC30 AMOXY/CLAV.ACID	5032384006533	63869
CT0225B	NET30 NETILMICIN	5032384006540	63834
CT0232B	SP100 SPIRAMYCIN	5032384006557	63834
CT0249B	CFP75 CEFOPERAZONE	5032384006564	63834
CT0263B	CFS30 CEFsulodin	5032384006588	63834
CT0264B	ATM30 AZTREONAM	5032384006595	63834
CT0406B	CXM5 CEFUROXIME	5032384006618	63834
CT0407B	CTX5 CEFOTAXIME	5032384006625	63834
CT0412B	CAZ30 CEFTAZIDIME	5032384006649	63834
CT0417B	CRO30 CEFTRIAXONE	5032384006656	63834
CT0424B	NET10 NETILMICIN	5032384006663	63834

Product Code	Product and Trade Name	Basic UDI	GMDN Code
CT0425B	CIP5 CIPROFLOXACIN	5032384006670	63834
CT0434B	NOR10 NORFLOXACIN	5032384006687	63834
CT0446B	OFX5 OFLOXACIN	5032384006694	63834
CT0453B	CFR30 CEFADROXIL	5032384006724	63834
CT0455B	IPM10 IMIPENEM	5032384006731	63834
CT0466B	MTZ50 METRONIDAZOLE	5032384006748	63834
CT0477B	ZOX30 CEFTIZOXIME	5032384006755	63834
CT0493B	FD5 FUSIDIC ACID	5032384006762	63834
CT0520B	SAM20 AMPICILLIN / SULBACTAM	5032384006779	63834
CT0522B	MUP5 MUPIROCIN	5032384006786	63834
CT0523B	MUP200 MUPIROCIN	5032384006793	63834
CT0538B	AMC3 AMOXY/CLAV.ACID	5032384006809	63834
CT0623B	CIP1 CIPROFLOXACIN	5032384006847	63834
CT0647B	TEC30 TEICOPLANIN	5032384006861	63834
CT0653B	CFM5 CEFIXIME	5032384006878	63834
CT0661B	PEF5 PEFLOXACIN	5032384006885	63834
CT0664B	CT50 COLISTIN SULPHATE	5032384006892	N/A
CT0665B	CEFOTETAN	5032384006908	63834
CT0668B	NOR5 NORFLOXACIN	5032384006922	63834
CT0693B	CLR15 CLARITHROMYCIN	5032384006946	63834
CT0695B	CN200 GENTAMICIN	5032384006953	63834
CT0725B	TZP110 PIPERACILLIN/TAZOBACTAM	5032384006977	63869
CT0758B	FOT200 FOSFOMYCIN/TROMETAMOL	5032384006984	63869
CT0771B	FEP30 CEFEPIME	5032384006991	63834
CT0774B	MEM10 MEROPENEM	5032384007004	63834
CT0794B	CN120 GENTAMICIN	5032384007011	63834
CT0906B	AZM15 AZITHROMYCIN	5032384068326	63834
CT0998B	BLANK CARTRIDGES	5032384007080	63834
CT1150S	PT15 PRISTINAMYCIN YARON	5032384008810	63834
CT1587B	LEV5 LEVOFLOXACIN	5032384079629	63834
CT1596B	CD01 ESBLs CEFPOD/CLAV ACID	5032384081813	63834
CT1599B	CLR2 CLARITHROMYCIN	5032384082018	63834
CT1612B	CPD10 CEFPODOXIME	5032384084012	63834

Product Code	Product and Trade Name	Basic UDI	GMDN Code
CT1615B	CIP10 CIPROFLOXACIN	5032384084616	63834
CT1616B	TZP36 PIPERACILLIN/TAZOBACTAM	5032384084623	63869
CT1617B	FD50 FUSIDIC ACID	5032384084630	63834
CT1618B	TOB30 TOBRAMYCIN	5032384084647	63834
CT1619B	PRL30 PIPERACILLIN	5032384084654	63834
CT1623B	CLR5 CLARITHROMYCIN	5032384085712	63834
CT1628B	TZP40 PIPERACILLIN/TAZOBACTAM	5032384088416	63869
CT1629B	CAZ10 CEFTAZIDIME	5032384088423	63834
CT1633B	MXF5 MOXIFLOXACIN	5032384090617	63834
CT1644B	QD15 QUINUPRISTIN/DALFOPRISTIN	5032384095223	63869
CT1649B	LZD10 LINEZOLID	5032384097616	63834
CT1650B	LZD30 LINEZOLID	5032384097623	63834
CT1653B	AMPICILLIN/SULBACTAM	5032384097715	63869
CT1661B	LOMEFLOXACIN	5032384099412	63834
CT1662B	CEFTIBUTEN	5032384099818	63834
CT1727B	CEFOPERAZONE/ SULBACTAM 2:1	5032384125241	63834
CT1743B	CEFTRIAZONE	5032384127436	63834
CT1749S	GENTAMICIN 500 (CN500)	5032384133031	63834
CT1761B	ERTAPENEM	5032384133710	63834
CT1806B	FLUCONAZOLE	5032384142644	63835
CT1807B	VORICONAZOLE	5032384142651	63835
CT1841B	TIGECYCLINE	5032384157716	63834
CT1870	CPD10 CEFPODOXIME 10	5032384186532	63834
CT1880B	DORIPENEM	5032384177660	63834
CT1895B	NAFCILLIN	5032384184835	63834
CT1897B	STREPTOMYCIN	5032384184859	63834
CT1941B	CEFTAROLINE	5032384445448	63834
CT1942B	CEFTAROLINE	5032384445455	63834
CT1947B	CEFTAZIDIME / AVIBACTAM (30/20) CZA50	5032384498864	63869
CT1948B	CEFTAZIDIME / AVIBACTAM (10/4) CZA14	5032384498871	63834
CT1949B	MEV30 MEROPENEM/VABORBACTAM	5032384506033	63834
CT1952B	TEMOCILLIN TEM30	5032384499113	63834
CT1964B	CEFIDERICOL	5032384526116	63834

Product Code	Product and Trade Name	Basic UDI	GMDN Code
CT1970B	CEFTOLOZANE/TAZOBACTAM C/T40	5032384526680	63834

Product Code	Product and Trade Name	Basic UDI	GMDN Code
ST1215	OXOID 12 PLACE DISC DISPENSER	5032384034819	35733
ST6090	DISC DISPENSER 6 PLACE 90MM SKIRT	5032384029723	35733
ST6100	DISC DISPENSER 6 PLACE 100MM SKIRT	5032384028900	35733
ST8090	DISC DISPENSER 8 PLACE 90MM SKIRT	5032384028467	35733
ST8100	DISC DISPENSER 8 PLACE 100MM SKIRT	5032384028917	35733