

## EU Declaration of Conformity

<b>Product Group</b>	Susceptibility (CT, ST) Test discs and dispensers for antibiotic susceptibility testing of microorganisms.
<b>Product Code and Product and trade name</b>	See attached product list
 <b>Legal Manufacturer</b>	Oxoid Ltd, Wade road, Basingstoke, Hampshire, RG24 8PW, United Kingdom
 <b>European Authorized representative</b>	Thermo Fisher Diagnostics B.V. Scheepsbouwersweg 1 B, 1121 PC Landsmeer, The Netherlands
<b>Risk Class</b>	Self-Declared – Non-Annex II Products and Not Self-Test Devices
<b>Conformity route</b>	ANNEX III

We, as the 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:** 

**Date:** 23 October 2020

**Name:** James Filer

**Function:** Vice President, Quality and Regulatory

**Issued in:** Basingstoke, Hampshire, UK

## Product list related to DoC Oxoid Ltd – Susceptibility

Product Code	Product and trade name
CT0002B	AMPICILLIN
CT0003B	AMPICILLIN
CT0004B	AMPICILLIN
CT0005B	BACITRACIN
CT0007B	CEPHALEXIN
CT0010B	CEPHALOTHIN
CT0011B	CEPHAZOLIN
CT0012B	CHLORAMPHENICOL
CT0013B	CHLORAMPHENICOL
CT0014B	CHLORAMPHENICOL
CT0015B	CLINDAMYCIN
CT0017B	COLISTIN
CT0018B	DOXYCYCLINE
CT0019B	ERYTHROMYCIN
CT0020B	ERYTHROMYCIN
CT0021B	ERYTHROMYCIN
CT0023B	FUSIDIC ACID
CT0024B	GENTAMICIN
CT0025B	KANAMYCIN
CT0026B	KANAMYCIN
CT0027B	LINCOMYCIN
CT0028B	LINCOMYCIN
CT0030B	MINOCYCLINE
CT0031B	NALIDIXIC ACID
CT0032B	NEOMYCIN
CT0033B	NEOMYCIN
CT0034B	NITROFURANTOIN
CT0035B	NITROFURANTOIN
CT0036B	NITROFURANTOIN
CT0037B	NOVOBIOCIN
CT0038B	NOVOBIOCIN
CT0039B	OLEANDOMYCIN
CT0040B	OXACILLIN
CT0042B	PENICILLIN G
CT0043B	PENICILLIN G
CT0044B	POLYMYXIN B
CT0047B	STREPTOMYCIN
CT0048B	STREPTOMYCIN
CT0051B	SULPHAMETHOXAZOLE
CT0052B	TRIMETHOPRIM/SULFAMETHOXAZOLE 1:19
CT0053B	TETRACYCLINE
CT0054B	TETRACYCLINE
CT0056B	TOBRAMYCIN
CT0057B	TRIMETHOPRIM
CT0058B	VANCOMYCIN
CT0059B	COMPOUND SULPHONAMIDES
CT0060B	AMOXYCILLIN
CT0061B	AMOXYCILLIN
CT0063B	CEPHRADINE
CT0064B	CLINDAMYCIN

Product Code	Product and trade name
CT0066B	ERYTHROMYCIN
CT0067B	METRONIDAZOLE
CT0069B	NITROFURANTOIN
CT0071B	FRAMYCETIN
CT0072B	GENTAMICIN
CT0073B	NYSTATIN
CT0074B	SULPHAMETHOXAZOLE
CT0075B	SULPHAFURAZOLE
CT0076B	TRIMETHOPRIM
CT0078B	RIFAMPICIN
CT0088B	PENICILLIN G
CT0091B	MECILLINAM
CT0096B	MECILLINAM
CT0104B	RIFAMPICIN
CT0107B	AMIKACIN
CT0108B	CEFAMANDOLE
CT0119B	CEFOXITIN
CT0123B	LINCOMYCIN
CT0124B	PENICILLIN G
CT0127B	CEFUROXIME SODIUM
CT0149B	CEFACTOR
CT0152B	PENICILLIN G
CT0159B	OXACILLIN
CT0161B	AMOXYCILLIN
CT0166B	CEFOTAXIME
CT0167B	TICARCILLIN
CT0174B	MEZLOCILLIN
CT0180B	PIPEMIDIC ACID
CT0181B	OXOLINIC ACID
CT0183B	FOSFOMYCIN
CT0188B	VANCOMYCIN
CT0192B	MEZLOCILLIN
CT0193B	CEFOPERAZONE
CT0199B	PIPERACILLIN
CT0207B	RIFAMPICIN
CT0223B	AMOXYCILLIN/CLAVULANIC ACID
CT0225B	NETILMICIN
CT0232B	SPIRAMYCIN
CT0249B	CEFOPERAZONE
CT0263B	CEFSULODIN
CT0264B	AZTREONAM
CT0406B	CEFUROXIME SODIUM
CT0407B	CEFOTAXIME
CT0412B	CEFTAZIDIME
CT0417B	CEFTRIAZONE
CT0424B	NETILMICIN
CT0425B	CIPROFLOXACIN
CT0434B	NORFLOXACIN
CT0446B	OFLOXACIN
CT0453B	CEFADROXIL
CT0455B	IMIPENEM
CT0466B	METRONIDAZOLE

Product Code	Product and trade name
CT0477B	CEFTIZOXIME
CT0493B	FUSIDIC ACID
CT0520B	AMPICILLIN/SULBACTAM
CT0522B	MUPIROCIN
CT0523B	MUPIROCIN
CT0538B	AMOXYCILLIN/CLAVULANIC ACID
CT0623B	CIPROFLOXACIN
CT0647B	TEICOPLANIN
CT0653B	CEFIXIME
CT0661B	PEFLOXACIN
CT0664B	COLISTIN
CT0665B	CEFOTETAN
CT0668B	NORFLOXACIN
CT0693B	CLARITHROMYCIN
CT0695B	GENTAMICIN
CT0725B	PIPERACILLIN/AZOBACTAM
CT0758B	FOSFOMYCIN/TROMETAMOL
CT0771B	CEFEPIME
CT0774B	MEROPENEM
CT0794B	GENTAMICIN
CT0906B	AZITHROMYCIN
CT0998B	BLANK CARTRIDGES
CT1150S	PT15 PRISTINAMYCIN
CT1587B	LEVOFLOXACIN
CT1599B	CLARITHROMYCIN
CT1612B	CEFPODOXIME
CT1615B	CIPROFLOXACIN
CT1616B	PIPERACILLIN/AZOBACTAM
CT1617B	FUSIDIC ACID
CT1618B	TOBRAMYCIN
CT1619B	PIPERACILLIN
CT1623B	CLARITHROMYCIN
CT1628B	PIPERACILLIN/AZOBACTAM
CT1629B	CEFTAZIDIME
CT1633B	MOXIFLOXACIN
CT1644B	QUINUPRISTIN/DALFOPRISTIN
CT1647B	CEFPROZIL
CT1649B	LINEZOLID
CT1650B	LINEZOLID
CT1653B	AMPICILLIN/SULBACTAM
CT1661B	LOMEFLOXACIN
CT1662B	CEFTIBUTEN
CT1727B	CEFOPERAZONE/ SULBACTAM 2:1
CT1743B	CEFTRIAZONE
CT1749S	GENTAMICIN 500 (CN500)
CT1761B	ERTAPENEM
CT1806B	FLUCONAZOLE
CT1807B	VORICONAZOLE
CT1841B	TIGECYCLINE
CT1880B	DORIPENEM
CT1895B	NAFCILLIN
CT1897B	STREPTOMYCIN

<b>Product Code</b>	<b>Product and trade name</b>
CT1941B	CEFTAROLINE
CT1942B	CEFTAROLINE
CT1947B	Ceftazidime / Avibactam (30/20) CZA50
CT1948B	Ceftazidime / Avibactam (10/4) CZA14
CT1949B	MEV30 Meropenem/Vaborbactam
CT1952B	TEMOCILLIN TEM30
CT1964B	Cefidericol
CT1970B	Ceftolozane/Tazobactam C/T40
ST1215	OXOID 12 PLACE DISC DISPENSER
ST6090	DISC DISPENSER 6 PLACE 90MM SKIRT
ST6100	DISC DISPENSER 6 PLACE 100MM SKIRT
ST8090	DISC DISPENSER 8 PLACE 90MM SKIRT
ST8100	DISC DISPENSER 8 PLACE 100MM SKIRT