
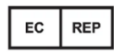


EU Declaration of Conformity

Product Group	Reagents (BR, SR) Supplemental and Biochemical reagents for preparing culture media, microbiological samples, or reagent conditions.
Product Code and Product and trade name	See attached product list
 Legal Manufacturer	Oxoid Ltd, 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 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:

12th April 2021

Name:

James Filer

Function:

Vice President, Quality and Regulatory

Issued in:

Basingstoke, Hampshire, UK

Product list related to DoC Oxoid Ltd – Reagents

Product Code	Product and trade name
BR0014G	PHOSPHATE BUFFERED SALINE TABLETS
BR0042A	ANAEROBIC CATALYST
BR0048G	THIOSULPHATE RINGERS TABLETS
BR0050A	BASIC FUCHSIN - TECHNICAL DYE
BR0052G	RINGERS SOLUTION TABLETS
BR0053G	SALINE TABLETS
BR0055B	ANAEROBIC INDICATOR
BR0066A	IDENT. TOUCH STICKS BETA-LACTAMASE
SR0020K	UREA 40%
SR0030J	POTASSIUM TELLURITE 3.5%
SR0035C,D	FILTERED HORSE SERUM
SR0042C	DEFIBRINATED SHEEP BLOOD
SR0047C	EGG YOLK EMULSION
SR0048C	LAKED HORSE BLOOD
SR0049C	OXALATED HORSE BLOOD
SR0050B,C,D,E,R	DEFIBRINATED HORSE BLOOD
SR0051B,C,D,E,R	DEFIBRINATED SHEEP BLOOD
SR0053B,C	SHEEP BLOOD IN ELSEVERS SOLUTION
SR0054C	EGG YOLK TELLURITE EMULSION
SR0059C	MYCOPLASMA SUPPLEMENT G
SR0060C	MYCOPLASMA SUPPLEMENT P
SR0069E,H	CAMPYLOBACTER SELECTIVE SUPPLEMENT (SKIRROW)
SR0070E	STAPH/STREP SELECTIVE SUPPLEMENT
SR0075E,H	DERMASEL SELECTIVE SUPPLEMENT
SR0078E,H	CHLORAMPHENICOL SELECTIVE SUPPLEMENT
SR0082E	BORDETELLA SELECTIVE SUPPLEMENT
SR0085E	CAMPYLOBACTER SELECTIVE SUPPLEMENT (BUTZLER)
SR0090A,H	VITOX SUPPLEMENT + RECONSTITUTION FLUID
SR0091E,H	V.C.N.T. SELECTIVE SUPPLEMENT
SR0095B,H	LCAT SELECTIVE SUPPLEMENT
SR0096E	CLOSTRIDIUM DIFFICILE SELECTIVE SUPPLEMENT
SR0098E	CAMPYLOBACTER SELECTIVE SUPPLEMENT (BLASER-WANG)
SR0099E	BACILLUS CEREUS SELECTIVE SUPPLEMENT
SR0101E	V.C.N. SELECTIVE SUPPLEMENT
SR0102E	PSEUDOMONAS C-N SELECTIVE SUPPLEMENT
SR0103E	PSEUDOMONAS C-F-C SELECTIVE SUPPLEMENT
SR0104B	V.C.A.T. SELECTIVE SUPPLEMENT
SR0105B	YEAST AUTOLYSATE SUPPLEMENT
SR0109E	YERSINIA SELECTIVE SUPPLEMENT
SR0112C	NITROCEFIN + RECONSTITUTION FLUID
SR0113E	BROAD SPECTRUM BETA-LACTAMASE MIX
SR0119E	GARDNERELLA VAGINALIS SELECTIVE SUPPLEMENT
SR0126E	STREPTOCOCCUS SELECTIVE SUPPLEMENT
SR0129B	PENASE
SR0136E	AMPICILLIN SELECTIVE SUPPLEMENT
SR0140B,E	LISTERIA SELECTIVE SUPPLEMENT (OXFORD)
SR0147E	H.PYLORI SELECTIVE SUPPLEMENT (DENT)
SR0155E,H	CCDA SELECTIVE SUPPLEMENT
SR0158E	HAEMOPHILUS TEST (HTM) SUPPLEMENT

SR0163H	NEOMYCIN SELECTIVE SUPPLEMENT
SR0167E	CAMPYLOBACTER SELECTIVE SUPPLEMENT (KARMALI)
SR0172E,H	CEFIXIME TELLURITE SELECTIVE SUPPLEMENT
SR0173E	CDMN SELECTIVE SUPPLEMENT
SR0174E	C.A.T. SELECTIVE SUPPLEMENT
SR0176G	MODIFIED CNA SELECTIVE SUPPLEMENT
SR0181E	NOVOBIOCIN SUPPLEMENT
SR0182H	YEAST AUTOLYSATE SUPPLEMENT
SR0184E	MEROPENEM SUPPLEMENT
SR0185E	GENTAMICIN SUPPLEMENT
SR0186E	VANCOMYCIN SUPPLEMENT
SR0189E	BURKHOLDERIA CEPACIA SELECTIVE SUPPLEMENT
SR0191E	CEFIXIME SUPPLEMENT
SR0194E	SALMONELLA SELECTIVE SUPPLEMENT
SR0195E	ORSAB SELECTIVE SUPPLEMENT
SR0204E	MODIFIED PRESTON CAMPYLOBACTER SUPPLEMENT
SR0205E	MODIFIED KARMALI SELECTIVE SUPPLEMENT
SR0231E	BRILLIANCE CANDIDA SELECTIVE SUPPLEMENT
SR0232E	CAMPYLOBACTER GROWTH SUPPLEMENT (LIQUID)
SR0233A	SPUTASOL (LIQUID)
SR0237C	XLT-4 SELECTIVE SUPPLEMENT
SR0247E	VANCOMYCIN SUPPLEMENT

Deklaracja zgodności UE

Grupa produktów	Odczynniki (BR, SR) Suplementy i odczynniki biochemiczne do przygotowywania pożywek hodowlanych, próbek mikrobiologicznych lub odczynników do badania warunków podobnych.
Kod produktu i nazwa handlowa	Patrz załączona lista produktów
 Producent prawny	Oxoid Ltd, Wade road, Basingstoke, Hampshire, RG24 8PW, Zjednoczone Królestwo
 Upoważniony reprezentant w UE	Thermo Fisher Diagnostics B.V. Scheepsbouwersweg 1 B, 1121 PC Landsmeer, Holandia
Klasa ryzyka	Deklaracja wytwórcy – produkty nie wymienione w załączniku II oraz nie przeznaczone do samokontroli
Szlak zgodności	Załącznik III

My, jako producent wyrobów, ponosimy wyłączną odpowiedzialność i niniejszym oświadczamy, że wymienione produkty są zgodne z postanowieniami dyrektywy WE 98/79/WE dotyczącej wyrobów medycznych do diagnostyki in vitro (IVDD).

Deklaracja ta jest wspierana przez System Zarządzania Jakością certyfikowany zgodnie z normą EN ISO 13485: 2016 (Certyfikat BSI nr MD 80930).

Podpis:

Data:

12 kwietnia 2021

Nazwisko: James Filer

Stanowisko: Vice President, Quality and Regulatory

Wydano w: Basingstoke, Hampshire,

Zjednoczone Królestwo

Lista produktów powiązana z Deklaracją DoC Oxoid Ltd - Odczynniki

Kod produktu	Produkt i nazwa handlowa
BR0014G	PHOSPHATE BUFFERED SALINE TABLETS
BR0042A	ANAEROBIC CATALYST
BR0048G	THIOSULPHATE RINGERS TABLETS
BR0050A	BASIC FUCHSIN – TECHNICAL DYE
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SR0078E.H	CHLORAMPHENICOL SELECTIVE SUPPLEMENT
SR0082E	BORDETELLA SELECTIVE SUPPLEMENT
SR0085E	CAMPYLOBACTER SELECTIVE SUPPLEMENT (BUTZLER)
SR0090A,H	VITOC SUPPLEMENT + RECONSTITUTION FLUID
SR0091E,H	V.C.N.T. SELECTIVE SUPPLEMENT
SR0095B,H	LCAT SELECTIVE SUPPLEMENT
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SR0101E	V.C.N. SELECTIVE SUPPLEMENT
SR0102E	PSEUDOMONAS C-N SELECTIVE SUPPLEMENT
SR0103E	PSEUDOMONAS C-F-C SELECTIVE SUPPLEMENT
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