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EU Declaration of Conformity

Name of Device / Product Group	Reagents (BR, SR)
Group Description	Supplemental and Biochemical reagents for preparing culture media, microbiological samples, or reagent conditions.
Product Code / Product and Trade Name	See attached product schedule
Legal Manufacturer	Oxoid Limited Wade Road, Basingstoke, Hampshire, RG24 8PW, UK SRN: GB-MF-000016914
EC REP European Authorized Representative	Thermo Fisher Diagnostics B.V. Scheepsbouwersweg 1 B, 1121 PC Landsmeer, NL SRN: NL-AR-000013157
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 80930

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)

Signature: Rul Shilling 24 July 2423

Name: Paul Sherlock

Function: Vice President, Quality Assurance and Regulatory Affairs

Issued in: United Kingdom

Effective Date: Refer to electronic signature





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The products related to MBD-BT-DOC-0026 Rev 9 - IVDR DOC Oxoid Ltd Class A (Reagents) are listed below:

Basic UDI-DI	Product Code	Product / Trade Name	Intended Use	UDI	GMDN Code	TF#
5032384RingersSolutionRS	BR0052G	RINGERS SOLUTION TABLETS	Ringers Solution (BR0052G) is used to prepare a general-purpose isotonic solution intended to be used for the dilution of microorganisms and as a diluent and for preparing suspensions of microbiological samples. Ringers Solution (BR0052G) is intended to be used in a diagnostic workflow to support the clinician in dilution of microorganisms from various sources where an isotonic solution is required.	5032384028610	43674	0233
5032384SalineTablets62	BR0053G	SALINE TABLETS	Saline Tablets (BR0053G) is used to prepare a general purpose 0.85% isotonic saline solution intended to be used for the dilution of microorganisms and as a diluent and for preparing suspensions of microbiological samples. Saline Tablets (BR0053G) is intended to be used in a diagnostic workflow to support the clinician in dilution of microorganisms from various sources where a 0.85% isotonic saline solution is required.	5032384028207	58673	0257
5032384AnaerobicIndiRJ	BR0055B	ANAEROBIC INDICATOR	Resazurin Anaerobic Indicator (BR0055B) is a cotton strip impregnated with resazurin used as a redox indicator. The strip is suitable for detecting redox conditions suitable for the growth of anaerobic organisms. This is an accessory to the anaerobic atmosphere generation systems.	5032384028658	43520	0190

Basic UDI-DI	Product Code	Product / Trade Name	Intended Use	UDI	GMDN Code	TF#
5032384Urea40OLWY	SR0020K	UREA 40% SOLUTION	Urea 40% Solution (SR0020K) is intended to be added to Thermo Scientific™ Oxoid™ Urea Agar Base (Dehydrated) (CM0053B) for the preparation of Christensen's medium. Christensen's medium is intended to be used to detect rapid urease activity of the Proteae and non-rapid urease activity of some Enterobacteriaceae in faecal and urine samples. Urea 40% Solution (SR0020K) is also intended to be used in the preparation of Thermo Scientific™ Oxoid™ Urea Broth Base (Dehydrated) (CM0071B), a liquid version of Christensen's medium intended for the differentiation of urease producing Enterobacteriaceae from members of the Salmonella and Shigella groups. Urea 40% Solution (SR0020K) used in the preparation of Christensen's media, is intended to be used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having Enterobacteriaceae infections.	5032384013845	58556	0156
5032384PotassTelluriteZ2	SR0030J	POTASSIUM TELLURITE 3.5%	Potassium Tellurite (SR0030J) is a selective supplement that is intended to be used in the preparation of Hoyle Medium Base (Dehydrated) (CM0083B) supplemented with Laked Horse Blood (SR0048C) for the isolation and differentiation of Corynebacterium diphtheriae types from wound and upper respiratory samples, including throat and nasal swabs.	5032384013876	58556	0201



Basic UDI-DI	Product Code	Product / Trade Name	Intended Use	UDI	GMDN Code	TF#
50202041 large Convert T	SR0035C	EII TEDED LIODOE CEDUM	Horse serum (SR0035C and SR0035D) devices are an extract of horse blood intended for use in a culture media preparation to isolate and differentiate clinical pathogens like Trichomonas vaginalis, Brucella species, Group B Streptococcus from	5032384029563	58556	0473
5032384HorseSerumLT	SR0035D	FILTERED HORSE SERUM	clinical samples like genito-urinary samples, blood, neonatal and vaginal samples etc. Horse serum (SR0035C and SR0035D) devices are used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having bacterial infections.	5032384127047		0473
5032384EggYolkEmulAN	SR0047C	EGG YOLK EMULSION	Egg Yolk Emulsion (SR0047C) is an enrichment supplement intended for use in culture media. It is intended to be added directly to nutrient media to aid the identification of organisms such as Clostridium, Bacillus and Staphylococcus species, by their lipase activity. Egg Yolk Emulsion (SR0047C), when added to Bacillus cereus Selective Agar Base (CM0617B), is intended to be used for the isolation of Bacillus cereus from faecal samples. Egg Yolk Emulsion (SR0047C), when added to Blood Agar Base (CM0055B and CM0055T), is intended to be used for the isolation of Staphylococcus and Clostridium species from clinical samples, including wound swabs. The device is intended to be used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having bacterial infections.	5032384013913	58556	0478
5032384LakedHBloodST	SR0048C	LAKED HORSE BLOOD	Laked Horse Blood (SR0048C) is an enrichment supplement intended for use in culture media preparations to isolate and differentiate clinical pathogens like Corynebacterium species, Staphylococcus species, Campylobacter species from clinical samples like respiratory secretion, cerebrospinal fluids, sputum, faecal samples, etc Laked Horse Blood is used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having bacterial infections.	5032384028429	58556	0471
	SR0050B		Defibrinated Horse Blood (SR0050B, SR0050C, SR0050D,	5032384028443		
	SR0050C		SR00505E, SR0050F and SR0050R) devices are enrichment supplements intended for use in a culture media preparation to isolate and differentiate clinical pathogens like Bacteroides	5032384029570		
5032384DefibHBloodLE	SR0050D	DEFIBRINATED HORSE BLOOD	species, Bordetella Pertussis, Haemophilus influenzae, Clostridium difficile, Staphylococcus species and Streptococcus species from clinical samples like	5032384128273	58556	0220
	SR0050E	DELIBRITATED HORSE BESOD	Streptococcus species from clinical samples like nasopharyngeal, respiratory secretions, blood, faecal samples, etc Defibrinated Horse Blood (SR0050B, SR0050C, SR0050D, SR00505E, SR0050F and SR0050P) devices are used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having bacterial infections.	5032384128280		
	SR0050F			5032384533541		
	SR0050R	50R		5032384142064		



Basic UDI-DI	Product Code	Product / Trade Name	Intended Use	UDI	GMDN Code	TF#
	SR0051B		Defibrinated Sheep Blood (SR0051) devices are general-	5032384028450	_	
	SR0051C		purpose enrichment supplements intended to be used in the preparation of many types of media for the isolation and culture of pathogenic and non-pathogenic microorganisms from	5032384124817		
5032384DefibSBloodQV	SR0051D	DEFIBRINATED SHEEP BLOOD	clinical samples (e.g., cerebral spinal fluid, pus and wound swabs, sputum, eye swabs, ear, nose and throat swabs, blood	5032384128297	58556	0472
	SR0051E		and faecal samples). Defibrinated Sheep Blood (SR0051) devices are used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected	5032384128303		
	SR0051R		of having bacterial infections.	5032384142057		
5032384MycoPlasAgarOL5S	SR0059C	MYCOPLASMA SUPPLEMENT G	Mycoplasma Supplement G (SR0059C) is a selective supplement intended to be used in the preparation of Mycoplasma medium for the isolation of Mycoplasma and Ureaplasma species from genital and respiratory samples.	5032384011377	58556	0186
5032384CampSelSupWE	SR0069E	CAMPYLOBACTER SEL. SUPP. (SKIRROW)	Thermo Scientific™ Campylobacter Selective Supplement (Skirrow) (SR0069E, SR0069H) are selective supplements intended to be used with Thermo Scientific™ Blood Agar Base No.2 (Dehydrated) (CM0271B, CM0271K, CM0271R and CM0271T) or Thermo Scientific™ Columbia Blood Agar Base (Dehydrated) (CM0331B, CM0331K, CM0331R and CM0331T) for the isolation of Campylobacter species from faecal samples. Campylobacter Selective Supplement (Skirrow) (SR0069E, SR0069H) are used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having Campylobacter infections.	5032384011407	58556	0153
3032364Camp3el3upvvL	SR0069H			5032384011414		0155
5032384StaphStrepSelSup62	SR0070E	STAPH/STREP SELECTIVE SUPPLEMENT	Staph/Strep Selective Supplement (SR0070E) is a selective supplement that may be used in the preparation of CNA Staph/Strep Medium for the selective isolation of Staphylococcus and Streptosoccus species from clinical samples (e.g. wounds, throat, genital, nose, groins, etc.). Staph/Strep Selective Supplement (SR0070E) is used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having bacterial infections.	5032384011421	58556	0239
5032384DermaselSuppDB	SR0075E	DERMASEL SELECTIVE SUPPLEMENT	Dermasel Selective Supplement (SR0075E) is a selective supplement that is intended to be used in the preparation of Dermasel Agar Base (Dehydrated) (CM0539B) for the isolation and identification of dermatophytes and other fungi from samples such as hair, skin scrapings and nails. Dermasel Selective Supplement (SR0075E) used in the preparation of Dermasel Agar Base (Dehydrated) (CM0539B) is intended to be used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having infections caused by dermatophytes and other fungi.	5032384011445	58556	0254



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5032384ChloramphenSupp38	SR0078E	SR me aid De CHLORAMPHENICOL SELECTIVE	Chloramphenicol Selective Supplement (SR0078E and SR0078H) is a selective supplement intended for use in culture media. It is intended to be added directly to nutrient media to aid in the isolation of fungi. When added to either Sabouraud Dextrose Agar (CM0041B, CM0041K, CM0041R and CM0041T) or Brain Heart Infusion Agar (CM1136B), it is intended to be used for the isolation of pathogenic fungi from	5032384011476	58556	0151
33233 (Gillotalliphoneapped	SR0078H	SUPPLEMENT	clinical samples, including skin, hair, nails, genital, respiratory and urine samples. Chloramphenicol Selective Supplement (SR0078E and SR0078H) is intended to be used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having fungal infections.	5032384011483	00000	0101
5032384BordetellaSelSupBU	SR0082E	BORDETELLA SELECTIVE SUPPLEMENT	Bordetella Selective Supplement (SR0082E) device is selective supplement that is used in the preparation of Bordetella medium for the isolation of Bordetella species from nasopharyngeal/pernasal samples and for subcultures. Bordetella Selective Supplement device is used in a diagnostic workflow to aid clinicians in determining potential treatment option for patients suspected of having bacterial infections.	5032384011490	58556	0112
5032384CampSelSupWE	SR0085E	CAMPYLOBACTER SEL. SUPP. (BUTZLER)	Thermo Fisher™ Oxoid™ Campylobacter Selective Supplement (Butzler) (SR0085E) is a selective supplement used in the preparation of Butzler medium for the isolation of Campylobacter species from faecal and food samples.	5032384011520	58556	0489
5032384VitoxSuppFluidS8	SR0090A	VITOX SUPPLEMENT +	The Vitox Supplement (SR0090A and SR0090H) devices are enrichment supplements intended to be used in the preparation of Thayer Martin medium using Thermo Scientific™ GC Agar Base (CM0367B, CM0367K, CM0367T, CM0367T, and CM0367V) for the isolation of pathogenic Neisseria and Haemophilus species from clinical samples (e.g., wounds, throat, genital, nose, etc). The Vitox Supplement (SR0090A and SR0090H) devices are used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having Neisseria and Haemophilus infections.	5032384011568	58556	0350
3032364 VIIOX3UPPI Tulu36	SR0090H	RECONSTITUTION FLUID		5032384011575	30330	0330
5032384CampSelSupWE	SR0098E	CAMPYLOBACTER SEL. SUPP. (BLASER-WANG)	Campylobacter Selective Supplement (Blaser-Wang) (SR0098E) is intended to be used for the preparation of Blaser-Wang selective medium for the isolation of Campylobacter species whilst inhibiting Candida species from faecal samples. Campylobacter Selective Supplement (Blaser-Wang) (SR0098E) is used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having Campylobacter infections.	5032384011674	58556	0483
5032384BCereusSelSuppXX	SR0099E	BACILLUS CEREUS SELECTIVE SUPPLEMENT	Thermo Scientific™ Polymyxin B Supplement (SR0099E) is a selective supplement that may be used in the preparation of PEMBA medium f or the isolation and enumeration of Bacillus cereus from faecal samples. It can also be used in the preparation of MYP agar f or testing food samples.	5032384011681	58556	0157



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5032384PseudoSelSupSZ	SR0102E	PSEUDOMONAS C-N SELECTIVE SUPPLEMENT	C-N Supplement (SR0102E) is a selective supplement that is intended to be used in the preparation of Pseudomonas Agar Base (Dehydrated) (CM0559B, CM0559R and CM0559T) for the isolation of Pseudomonas spp. from a wide range of clinical samples including urine, wound swabs, and sputum. This supplement is recommended for the selective isolation of Pseudomonas aeruginosa. C-N Supplement (SR0102E) is used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having Pseudomonas infections.	5032384011711	58556	0175
5032384PseudSelCFCSuppUE	SR0103E	PSEUDOMONAS C-F-C SELECTIVE SUPPLEMENT	C-F-C Supplement (SR0103E) is a selective supplement that may be used in the preparation of Pseudomonas Agar Base (Dehydrated) (CM055B, CM0559R and CM0559T) for the isolation of Pseudomonas spp. from a wide range of clinical samples including urine, wound swabs, and sputum. Pseudomonas C-F-C Supplement (SR0103E) is recommended for the selective isolation of Pseudomonas spp. generally. C-F-C Supplement (SR0103E) is used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having Pseudomonas infections.	5032384011728	58556	0175
5032384YersiniaAgarOLY9	SR0109E	YERSINIA SELECTIVE SUPPLEMENT	Yersinia Selective Supplement (SR0109E) is a selective supplement that is intended to be used in the preparation of Yersinia Selective Agar Base (Dehydrated) (CM0653B and CM0653T) for the isolation of Yersinia enterocolitica from faecal samples. Yersinia Selective Supplement (SR0109E), when added to Yersinia Selective Agar Base (Dehydrated) (CM0653B and CM0653T), is intended to be used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having yersiniosis.	5032384011803	58556	0196
5032384NitrocefinRecFldZF	SR0112C	NITROCEFIN + RECONSTITUTION FLUID	Thermo Scientific™ Oxoid™ Nitrocefin Solution (SR0112C) is a reagent for the rapid detection of beta-lactamase production in microorganisms. Nitrocefin Solution (SR0112C) is intended to be used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of being infected with microorganisms which possess beta-lactamase activity.	5032384011872	58556	0262
5032384BrdSpecBetaLact6Q	SR0113E	BROAD SPECTRUM BETA-LACTAMASE MIXTURE	Broad Spectrum Beta-Lactamase Mixture (SR0113E) is a reagent that may be used to inactivate beta-lactam antibiotics in blood samples prior to microbiological examination or to inactivate beta-lactam antibiotics in blood samples prior to the assay of aminoglycosides or other non-lactam antibiotics.	5032384011889	58556	0247



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5032384GardnerSelSupYD	SR0119E	GARDNERELLA VAGINALIS SELECTIVE SUPPLEMENT	The Thermo Scientific™ Gardnerella Vaginalis Selective Supplement (SR0119E) is a selective supplement intended to be used in the preparation of Gardnerella vaginalis selective medium for the isolation of Gardnerella vaginalis from genital samples. The device is used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having infections caused by Gardnerella vaginalis.	5032384011933	58556	0501
5032384StrepSelSupAW	SR0126E	STREPTOCOCCUS SELECTIVE SUPPLEMENT	Streptococcus Supplement (SR0126E) is a selective supplement that may be used for the preparation of Streptococcal C.O.B.A. (Colistin sulphate Oxolinic acid Blood Agar) selective medium for the isolation of Streptococcus species from clinical samples (e.g., throat, wounds, and burns). Streptococcus Supplement (SR0126E) is used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having streptococcal infections.	5032384011988	58556	0218
5032384Penase1Vial8X	SR0129B	PENASE	The Thermo Scientific™ Penase (SR0129B) is a reagent intended to be used to inactivate penicillin in blood or other tissue samples prior to microbiological examination or prior to the assay of aminoglycosides or other non-lactam antibiotics. It can also be used in specific sterility testing applications. The device is used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients affected by bacterial infections.	5032384013944	58237	0252
5032384CCDASelMedOLP	SR0155E	CCDA SELECTIVE SUPPLEMENT	CCDA Selective Supplement (SR0155E and SR0155H) is a selective supplement intended to be used in the preparation of Campylobacter Blood-Free Selective Agar (CCDA) (Dehydrated) (CM0739B, CM0739R and CM0739T) for the isolation of Campylobacter species from faecal samples.	5032384012176	50550	0170
5032364CCDASeliviedOLP	SR0155H	CCDA SELECTIVE SUPPLEMENT	Campylobacter Selective Agar (PO0119A, CM0739B, CM0739R, CM0739T, SR0155E and SR0155H) are intended to be used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having campylobacteriosis.	5032384012183	58556	0170
5032384HaemophTestSup7B	SR0158E	HAEMOPHILUS TEST (HTM) SUPPLEMENT	HTM Supplement (SR0158E) is an enrichment supplement used in the preparation of Haemophilus Test Medium (HTM) Base (CM0898B) for the susceptibility testing of Haemophilus species isolated from clinical samples. The device is used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having Haemophilus infections.	5032384012213	58556	0237
5032384NeoSelSup35	SR0163H	NEOMYCIN SELECTIVE SUPPLEMENT	Neomycin Selective Supplement (SR0163H) is a selective supplement used for addition to culture media such as Wilkins-Chalgren Anaerobe Agar (CM0619) or Anaerobe Basal Agar (CM0972) to facilitate growth of Clostridia and other anaerobes from clinical samples, such as soft tissue and skin.	5032384012244	58556	0224



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5032384CampSelSupWE	SR0167E	CAMPYLOBACTER SEL. SUPP. (KARMALI)	Karmali Campylobacter Selective Supplement (SR0167E) and Modified Karmali Selective Supplement (SR0205E) devices are selective supplements that are intended to be used in the preparation of Campylobacter Karmali Agar Base (CM0935B) for the isolation of Campylobacter species from faecal samples. Karmali Campylobacter Selective Supplement (SR0167E) and Modified Karmali Selective Supplement (SR0205E) devices, when added to Campylobacter Karmali Agar Base (CM0935B), are intended to be used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having Campylobacter infections.	5032384012312	58556	0211
5032384CefixTellSuppU6	SR0172E	CEFIXIME TELLURITE SELECTIVE	C-T Supplement (SR0172E and SR0172H) devices are a selective supplement that may be used in the preparation of Sorbitol MacConkey Agar (Dehydrated) (CM0813B) or Sorbitol MacConkey Agar (SMAC) with chromogen 5-bromo-4-chloro-3-indOolyl-b-D-glucuronide (BCIG) (Dehydrated) (CM0981B) for	5032384029136	58556	0207
3032304Celix1eli3upp00	SR0172H	SUPPLEMENT	the detection of E. coli 0157:H7 in faecal and urine samples. C-T Supplement (SR0172E and SR0172H) devices are used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having E. coli infections.	5032384032624	36336	0207
5032384ModCNASelSupp4Y	SR0176G	MODIFIED CNA SELECTIVE SUPPLEMENT	Modified CNA Selective Supplement (SR0176G) is a selective supplement intended to be used in the preparation of Modified CNA Staph/Strep medium using Columbia Blood Agar Base (CM0331) or Blood Agar Base No.2 (CM271) with defibrinated horse blood or sheep blood added, for the growth of Grampositive microorganisms from clinical samples (e.g., wounds, throat, genital, nose, etc.). Modified CNA Selective Supplement (SR0176G) is used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having Gram-positive infections.	5032384014613	58556	0450
5032384NovobiosuppJU	SR0181E	NOVOBIOCIN SUPPLEMENT	Novobiocin Selective Supplement (SR0181E) is a selective supplement intended for use in culture media. Novobiocin Selective Supplement (SR0181E) is intended to be used in the preparation of Modified Tryptone Soya Broth (CM0989B and CM0989G) for the selective enrichment of Escherichia coli O157 from faecal samples. Novobiocin Selective Supplement (SR0181E), when added to Modified Tryptone Soya Broth (CM0989B and CM0989G), is intended to be used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having E. coli O157 infections.	5032384033416	58556	0192
5032384BurkCepSuppJB	SR0189E	BURKHOLDERIA CEPACIA SEL. SUPP.	A selective supplement that may be used in the preparation of Burkholderia cepacia medium for the isolation of Burkholderia cepacia from respiratory samples. Can also be used for testing non-sterile inorganic salt solutions with preservative. Required for the Culture Media for use in in vitro diagnostic procedures	5032384068340	58556	0228



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5032384SalmonelSelSupR8	SR0194E	SALMONELLA SELECTIVE SUPPLEMENT	Salmonella Selective Supplement (SR0194E) is intended to be used as a selective supplement that is used in the preparation of Chromogenic Salmonella Agar Base (Dehydrated) (CM1007B and CM1007T) and Brilliance Salmonella Agar Base (Dehydrated) (CM1092B and CM1092T) for the presumptive identification of Salmonella species from faecal samples. Salmonella Selective Supplement (SR0194E) is intended to be used as a selective supplement that is used in the preparation of Chromogenic Salmonella Agar Base (Dehydrated) (CM1007B and CM1007T) and Brilliance Salmonella Agar Base (Dehydrated) (CM1092B and CM1092T) in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having Salmonella infection.	5032384090730	58556	0459
5032384ModPrestCampSupBF	SR0204E	MODIFIED PRESTON CAMPYLOBACTER SUPPL.	Modified Preston Campylobacter Selective Supplement (SR0204E) is a selective supplement intended to be used in the preparation of Preston Campylobacter selective medium for the isolation of Campylobacter species from faecal samples. When Thermo Scientific™ Oxoid™ Campylobacter Agar Base (CM0689B) is supplemented with Modified Preston Campylobacter Selective Supplement (SR0204E) it is intended to be used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having bacterial gastroenteritis.	5032384084715	58556	0199
5032384KarmaliSelSup3S	SR0205E	MODIFIED KARMALI SELECTIVE SUPPLEMENT	Karmali Campylobacter Selective Supplement (SR0167E) and Modified Karmali Selective Supplement (SR0205E) devices are selective supplements that are intended to be used in the preparation of Campylobacter Karmali Agar Base (CM0935B) for the isolation of Campylobacter species from faecal samples. Karmali Campylobacter Selective Supplement (SR0167E) and Modified Karmali Selective Supplement (SR0205E) devices, when added to Campylobacter Karmali Agar Base (CM0935B), are intended to be used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having Campylobacter infections.	5032384085811	58556	0211
5032384CampSelSupWE	SR0232E	CAMPYLOBACTER GROWTH SUPPL. (LIQUID)	Campylobacter Growth Supplement (Liquid) (SR0232E) is a supplement intended to be used in the preparation of a variety of media for the enhanced growth and aerotolerance of Campylobacter spp. from faecal samples. Campylobacter Growth Supplement (Liquid) (SR0232E) is used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having bacterial infections.	5032384131716	58556	0135
5032384SputasolY5	SR0233A	SPUTASOL (LIQUID)	The Thermo Scientific™ Sputasol (Liquid) (SR0233A) is a reagent intended to be used for the liquefaction of sputum samples before microbiological testing. The device is used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients affected by bacterial infections.	5032384132423	58556	0212



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Basic UDI-DI	Product Code	Product / Trade Name	Intended Use	UDI	GMDN Code	TF#
5032384XLT4SelSUpSR	SR0237C	XLT-4 SELECTIVE SUPPLEMENT	XLT-4 Selective Supplement (SR0237C) is a selective supplement that is intended to be used in conjunction with XLT-4 Agar Base (CM1061B, CM1061T) for the isolation and identification of Salmonella species from faecal samples. XLT-4 Agar (PO1158A), XLT-4 Agar Base (CM1061B, CM1061T) and XLT-4 Selective Supplement (SR0237C) devices are intended to be used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having infections caused by Salmonella species.	5032384139811	58556	0242

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