


EU Declaration of Conformity

Name of Device / Product Group	IVDR Class A		
Product Description	See attached product schedule		
Product Code / Product and Trade Name	See attached product schedule		
 Legal Manufacturer	Remel, Inc., 12076 Santa Fe Trail Drive, Lenexa, Kansas, 66215, USA SRN: Not yet available		
<table border="1" data-bbox="130 779 325 837"> <tr> <td>EC</td> <td>REP</td> </tr> </table> European Authorized Representative	EC	REP	Thermo Fisher Diagnostics B.V. Scheepsbouwersweg 1 B, 1121 PC Landsmeer, NL SRN: NL-AR-000013157
EC	REP		
UK Responsible Person:	Oxoid Ltd, Wade Road, Basingstoke, RG24 8PW, UK		
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 the IVDR		
Certificate(s) Issued	EN ISO 13485:2016 – FM 586933		

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:

Name:

Function: Regulatory Affairs

Product Schedule

The products related to MBD EU IVDR Declaration of Conformity - Class A (Rev 4) are listed below:

Basic UDI-DI	Product Code	Product / Trade Name	Intended Use	UDI	GMDN Code	TF #
8488380M4RTA3	EB1348B	MICROTEST M4RT (3ML) WITHOUT BEADS	MicroTest M4RT (herein referred to as MicroTest M4RT) is a liquid medium recommended for the transport of clinical specimens to the laboratory for microbiological procedures for viral and chlamydial agents. The device is used in a diagnostic workflow to aid clinicians in the treatment options for patients suspected of having viral and bacterial infections.	5032384530151	62392	0404
	EB1348I	MICROTEST M4RT (1 ML) WITHOUT BEADS		5032384540372		
	EB1367B	MICROTEST M4RT (3ML) WITHOUT BEADS		5032384544417		

Basic UDI-DI	Product Code	Product / Trade Name	Intended Use	UDI	GMDN Code	TF #
8488380M4RTA3	R12505	MICROTEST M4RT (3ML) TUBE, RED PK/72	MicroTest M4RT (herein referred to as MicroTest M4RT) is a liquid medium recommended for the transport of clinical specimens to the laboratory for microbiological procedures for viral and chlamydial agents. The device is used in a diagnostic workflow to aid clinicians in the treatment options for patients suspected of having viral and bacterial infections.	848838018336	62392	0404
8488380MicroTestKitAG	R12530	MICROTEST M6 (1.5 ML) UNIVERSAL SWAB KIT PK/7	MicroTest M5 and M6 are liquid media recommended for the transport of clinical specimens to the laboratory for microbiological procedures for viruses, chlamydia, and mycoplasmas, which include Mycoplasma and Ureaplasma species. The devices are used in a diagnostic workflow to aid clinicians in the treatment options for patients suspected of having viral and bacterial infections.	848838072710	62392	0467
	R12533	MICROTEST M6 (3 ML) UNIVERSAL SWAB KIT PK/72		848838078132		
8488380M4RTA3	R12552	MICROTEST M4RT (3ML) TRADITIONAL SWAB KIT PK/100	MicroTest M4RT (herein referred to as MicroTest M4RT) is a liquid medium recommended for the transport of clinical specimens to the laboratory for microbiological procedures for viral and chlamydial agents. The device is used in a diagnostic workflow to aid clinicians in the treatment options for patients suspected of having viral and bacterial infections.	848838018411	62392	0404
8488380MicroTestKitAG	R12555	MICROTEST M5 (3 ML) TRADITIONAL SWAB KIT PK/100	MicroTest M5 and M6 are liquid media recommended for the transport of clinical specimens to the laboratory for microbiological procedures for viruses, chlamydia, and mycoplasmas, which include Mycoplasma and Ureaplasma species. The devices are used in a diagnostic workflow to aid clinicians in the treatment options for patients suspected of having viral and bacterial infections.	848838018442	62392	0467
	R12557	MICROTEST M6 (1.5 ML) TRADITIONAL SWAB KIT PK/100		848838072758		
	R12560	MICROTEST M6 (1.5 ML) TRADITIONAL-TIPPED FLOCKED SWAB KIT PK/100		848838075018		
	R12561	MICROTEST M6 (1.5 ML) MICRO-TIPPED FLOCKED SWAB KIT PK/100		848838074936		

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Basic UDI-DI	Product Code	Product / Trade Name	Intended Use	UDI	GMDN Code	TF #
8488380MicroTestKitAG	R12562	MICROTEST M6 (1.5 ML) UNIVERSAL SWAB KIT PK/100	MicroTest M5 and M6 are liquid media recommended for the transport of clinical specimens to the laboratory for microbiological procedures for viruses, chlamydia, and mycoplasmas, which include Mycoplasma and Ureaplasma species. The devices are used in a diagnostic workflow to aid clinicians in the treatment options for patients suspected of having viral and bacterial infections.	848838074943	62392	0467
	R12563	MICROTEST M6 (3 ML) UNIVERSAL SWAB KIT PK/100		848838078637		
8488380M4RTA3	R12565	MICROTEST M4RT (3ML) TRADITIONAL FLOCK SWAB KIT PK/100	MicroTest M4RT (herein referred to as MicroTest M4RT) is a liquid medium recommended for the transport of clinical specimens to the laboratory for microbiological procedures for viral and chlamydial agents. The device is used in a diagnostic workflow to aid clinicians in the treatment options for patients suspected of having viral and bacterial infections.	848838074967	62392	0404
	R12566	MICROTEST M4RT (3ML) MICROTIP FLOCK SWAB KIT PK/100		848838074974		
	R12567	MICROTEST M4RT (3ML) UNIVERSAL FLOCK SWAB KIT PK/100		848838074844		
8488380MicroTestKitAG	R12568	MICROTEST M6 (3 ML) TRADITIONAL-TIPPED FLOCKED SWAB KIT PK/100	MicroTest M5 and M6 are liquid media recommended for the transport of clinical specimens to the laboratory for microbiological procedures for viruses, chlamydia, and mycoplasmas, which include Mycoplasma and Ureaplasma species. The devices are used in a diagnostic workflow to aid clinicians in the treatment options for patients suspected of having viral and bacterial infections.	848838078125	62392	0467
	R12569	MICROTEST M6 (3 ML) MICRO-TIPPED FLOCKED SWAB KIT PK/100		848838078149		
8488380M4RTA3	R12576	MICROTEST M4RT (3ML) UNIVERSAL PLUS SWAB KIT PK/100	MicroTest M4RT (herein referred to as MicroTest M4RT) is a liquid medium recommended for the transport of clinical specimens to the laboratory for microbiological procedures for viral and chlamydial agents. The device is used in a diagnostic workflow to aid clinicians in the treatment options for patients suspected of having viral and bacterial infections.	848838018510	62392	0404
	R12578	MICROTEST M4RT (3ML) UNIVERSAL SWAB KIT PK/100		848838018534		
8488380MicroTestKitAG	R12580	MICROTEST M5 (3 ML) UNIVERSAL SWAB KIT PK/100	MicroTest M5 and M6 are liquid media recommended for the transport of clinical specimens to the laboratory for microbiological procedures for viruses, chlamydia, and mycoplasmas, which include Mycoplasma and Ureaplasma species. The devices are used in a diagnostic workflow to aid clinicians in the treatment options for patients suspected of having viral and bacterial infections.	848838018558	62392	0467
	R12582	MICROTEST M6 (1.5 ML) UNIVERSAL SWAB KIT PK/100		848838072772		
8488380M4RTA3	R12587	MICROTEST M4RT (3ML) TUBE PK/72	MicroTest M4RT (herein referred to as MicroTest M4RT) is a liquid medium recommended for the transport of clinical specimens to the laboratory for microbiological procedures for viral and chlamydial agents. The device is used in a diagnostic workflow to aid clinicians in the treatment options for patients suspected of having viral and bacterial infections.	842558107004	62392	0404
	R12588	MICROTEST M4RT (3ML) FLOCKED SWAB KIT PK/100		842558106939		

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Basic UDI-DI	Product Code	Product / Trade Name	Intended Use	UDI	GMDN Code	TF #
8488380M4RTA3	R12700	MICROTEST™ M4RT (3ML) W/O BEADS TUBE, RED PK/72	MicroTest M4RT (herein referred to as MicroTest M4RT) is a liquid medium recommended for the transport of clinical specimens to the laboratory for microbiological procedures for viral and chlamydial agents. The device is used in a diagnostic workflow to aid clinicians in the treatment options for patients suspected of having viral and bacterial infections.	842558108919	62392	0404
	R12705	MICROTEST™ M4RT (3ML) W/O BEADS NP SWAB KIT PK/ 100		842558109527		
	R12900	MICROTEST™ M4RT (3ML) DUAL SWAB KIT PK/72		842558109718		
8488380CoagulasePlasmaLJ	R21050	COAGULASE PLASMA 5ML	Coagulase Plasma is a reagent for use in qualitative procedures for the detection of coagulase enzyme in staphylococci. The device is used in a diagnostic workflow to aid clinicians in the treatment options for patients suspected of having bacterial infections.	848838022227	42737	0388
	R21051	COAGULASE PLASMA 15ML		848838022241		
	R21052	COAGULASE PLASMA 25ML		848838022258		
	R21060	COAGULASE PLASMA 5ML PK/6		848838022265		
8488380HippurateDiskTV	R21085	HIPPURATE DISK	The Hippurate Disk is a reagent-impregnated disk for use in qualitative procedures to detect the hydrolysis of sodium hippurate by hippuricase. The device is used as an aid to the presumptive identification of Group B streptococci (Streptococcus agalactiae), Gardnerella vaginalis and Campylobacter jejuni.	848838022333	43702	0391
8488380BactiCardCandida8B	R21106	BACTICARD CANDIDA	A rapid, qualitative, enzymatic test for the presumptive identification of Candida albicans grown on plated media by the detection of L-proline aminopeptidase and β-galactosaminidase. The device is used in a diagnostic workflow to aid clinicians in the treatment options for patients suspected of having Candidiasis	848838022432	30666	0392
8488380BctCrdEcoliHQ	R21108	BACTICARD E. COLI	A rapid, qualitative, enzymatic test for the presumptive identification of Escherichia coli grown on plated media by the detection of tryptophanase and β-glucuronidase. The device is used in a diagnostic workflow to aid clinicians in the treatment options for patients suspected of having bacterial infections.	848838022456	50417	0392
8488380BctCrdNeisseriaBV	R21110	BACTICARD NEISSERIA	A rapid, qualitative, enzymatic test for the presumptive identification of Neisseria species grown on plated media by the detection of β-galactosidase, indoxyl butyrate esterase, gamma-glutamyl aminopeptidase and prolylaminopeptidase. The device is used in a diagnostic workflow to aid clinicians in the treatment options for patients suspected of having bacterial infections.	848838022470	52805	0392
8488380BactiCardStrep3A	R21112	BACTICARD STREP	A rapid, qualitative, enzymatic test for the presumptive identification of Streptococcus species and related genera grown on plated media by the detection of leucine aminopeptidase, pyroglutamyl aminopeptidase and esculin hydrolysis. The device is used in a diagnostic workflow to aid clinicians in the treatment options for patients suspected of having bacterial infections.	848838022494	51701	0392

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8488380CatarrhalisDiskQMc	R21121	CATARRHALIS TEST DISK	The Catarrhalis Test Disk is a disk impregnated with indoxyl butyrate for use in qualitative procedures for the presumptive identification of Moraxella catarrhalis by detection of butyrate esterase. The device is used in a diagnostic workflow to aid clinicians in the treatment options for patients suspected of having bacterial infections.	848838022593	43508	0395
8488380MicrodaseDiskAG	R21132	MICRODASE DISK	The Microdase Disk is a reagent-impregnated disk for use in qualitative procedures to aid in the differentiation of Staphylococcus species from Micrococcus species by the detection of the oxidase enzyme. The device is used in a diagnostic workflow to aid clinicians in the treatment options for patients suspected of having bacterial infections.	848838022746	50421	0389
8488380BactiDrpReagentsY6	R21502	BACTIDROP ACRIDINE ORANGE	BactiDrop Acridine Orange is a fluorescent stain for use in qualitative procedures for the microscopic detection of microorganisms in clinical samples and blood cultures.	848838023743	43587	0383
	R21507	BACTIDROP CALCOFLUOR WHITE	BactiDrop Calcofluor White is a fluorescent stain for use in qualitative procedures for the microscopic detection of fungal elements, yeasts, Acanthamoeba cysts, microsporidia and Pneumocystis carinii in clinical samples.	848838023750		
	R21508	BACTIDROP DESOXYCHOLATE (10%)	BactiDrop Desoxycholate (10%) is a reagent used in qualitative procedures for the detection of bile solubility for the differentiation of Streptococcus pneumoniae from other alpha haemolytic streptococci.	848838023767	42735	
	R21510	BACTIDROP DOBELL & O'CONNOR IODINE	BactiDrop Dobell & O'Connor Iodine is a stain used for the microscopic examination of faecal samples for the detection of intestinal protozoa.	848838023774	63816	
	R21514	BACTIDROP FERRIC CHLORIDE (10%)	BactiDrop Ferric Chloride (10%) is a reagent for use in qualitative procedures for the detection of deamination of phenylalanine by microorganisms.	848838023781	53514	
	R21518	BACTIDROP INDIA INK	BactiDrop India Ink is a stain for the microscopic examination of encapsulated microorganisms in clinical samples.	848838023798	43587	
	R21522	BACTIDROP INDOLE (KOVACS)	BactiDrop Indole (Kovacs') is a reagent for use in qualitative procedures for the detection of indole production by microorganisms grown in indole broth.	848838023811	43720	
	R21524	BACTIDROP KOH (10%)	BactiDrop Potassium Hydroxide (10%) is reagent used in the initial preparation of clinical samples for microscopic examination to detect fungal elements.	848838023828		
	R21526	BACTIDROP LACTOPHENOL	BactiDrop Lactophenol Aniline Blue is a stain used for the microscopic detection of fungal elements.	848838023835	43587	
	R21528	BACTIDROP LUGOL'S IODINE	BactiDrop Lugol's Iodine is a stain used for the microscopic examination of faecal samples for the detection of intestinal parasites. Can be used in conjunction with Trichrome stain.	848838023842		
	R21534	BACTIDROP NINHYDRIN	BactiDrop Ninhydrin is a reagent for use in qualitative procedures for the detection of the ability of a microorganism to hydrolyse sodium hippurate.	848838023859	35841	

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8488380BactiDrpReagentsY6	R21536	BACTIDROP NITRATE A	BactiDrop Nitrate A is a reagent for the detection of the ability of a microorganism to reduce nitrate to nitrite or free nitrogen gas as part of a two-step qualitative procedure.	848838023866	35841	0383
	R21538	BACTIDROP NITRATE B	BactiDrop Nitrate B is a reagent for the detection of the ability of a microorganism to reduce nitrate to nitrite or free nitrogen gas as part of a two-step qualitative procedure.	848838023873		
	R21540	BACTIDROP OXIDASE	BactiDrop Oxidase is a reagent for use in qualitative procedures for the detection of the cytochrome oxidase enzyme activity in microorganisms.	848838023880	38062	
	R21550	BACTIDROP SPOT INDOLE	BactiDrop Spot Indole is a reagent for use in qualitative procedures to detect the ability of a microorganism to spilt indole from tryptophan.	848838023903	43720	
	R21560	BACTIDROP VOGES-PROSKAUER A	BactiDrop Voges-Proskauer A is a reagent for use as part of a two-step qualitative procedure for the detection of the ability of a microorganism to produce acetylmethylcarbinol (acetoin) from glucose fermentation.	848838023910	43509	
	R21562	BACTIDROP VOGES-PROSKAUER B	BactiDrop Voges-Proskauer B is a reagent for use as part of a two-step qualitative procedure for the detection of the ability of a microorganism to produce acetylmethylcarbinol (acetoin) from glucose fermentation.	848838023927		
8488380NitrocefinDisk47	R211667	NITROCEFEN DISK	The Nitrocefin Disk is a disk impregnated with nitrocefin for use in qualitative procedures for the detection of β-lactamase produced by bacterial isolates. The device is used in a diagnostic workflow to aid clinicians in the treatment options for patients suspected of having bacterial infections.	848838023088	42733	0387

Basic UDI-DI	Product Code	Product / Trade Name	Intended Use	UDI	GMDN Code	TF #
8488380LAPDiskJR	R30168501	LAP 50 TEST KIT	The LAP Test Kit is a rapid, colorimetric test for use in qualitative procedures for the detection of leucine aminopeptidase activity in isolates of streptococci and related genera. The device is used in a diagnostic workflow to aid clinicians in treatment options for patients suspected of having bacterial infections.	848838028625	30666	0393
8488380PYRDiskXB	R30854301	PYR 50 TEST KIT	The PYR Disk is a rapid, colorimetric test for use in qualitative procedures for the presumptive identification of enterococci, group A streptococci and Escherichia coli by detection of pyrrolidonyl arylamidase (PYRase). The device is used in a diagnostic workflow to aid clinicians in the treatment options for patients suspected of having bacterial infections.	848838028892	30666	0382
	R30854401	PYR 100 TEST KIT		848838028915		
8488380Pathotec7W	R38191	PATHOTEC CO (CYTOCHROME OXIDASE)	The Pathotec CO (cytochrome oxidase), is a reagent impregnated paper strip for use in qualitative procedures for the detection of the enzyme cytochrome oxidase activity in bacteria grown on plated media. The device is used in a diagnostic workflow to aid clinicians in the treatment options for patients suspected of having bacterial infections.	848838031151	38062	0390

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Basic UDI-DI	Product Code	Product / Trade Name	Intended Use	UDI	GMDN Code	TF #
8488380GramStainRY	R40052	GRAM CRYSTAL VIOLET 250ML	A reagent/set of reagents used in a technique for the differentiation of Gram-negative and Gram-positive microorganisms.	848838065552	43733	0381
	R40053	GRAM CRYSTAL VIOLET 250MLX5		848838065569		
	R40054	GRAM DECOLORIZER 250ML		848838065576		
	R40055	GRAM DECOLORIZER 250MLX5		848838065583		
	R40056	GRAM IODINE 250ML		848838065590		
	R40057	GRAM IODINE 250MLX5		848838065606		
	R40058	GRAM SAFRANIN 250ML		848838065613		
8488380GramStainRY	R40059	GRAM SAFRANIN 250MLX5	A reagent/set of reagents used in a technique for the differentiation of Gram-negative and Gram-positive microorganisms.	848838065620	43733	0381
	R40073	GRAM CRYSTAL VIOLET 1GAL		848838065651		
	R40075	GRAM DECOLORIZER 1GAL		848838065668		
	R40077	GRAM IODINE 1GAL		848838065675		
	R40079	GRAM SAFRANIN 1GAL		848838065682		
	R40080	GRAM STAIN KIT		848838065699		

Basic UDI-DI	Product Code	Product / Trade Name	Intended Use	UDI	GMDN Code	TF #
8488380RapIDReagentsKD	R8309002	RAPID INDOLE REAGENT	RapID Spot Indole is a reagent to be used with the RapID manual identification systems.	848838057830	43720	0363
	R8309003	RAPID NITRATE A REAGENT	RapID Nitrate A Reagent (R8309003) and RapID Nitrate B Reagent (R8309004) are accessory reagents to be used with the RapID manual identification systems.	848838057878	35841	
	R8309004	RAPID NITRATE B REAGENT		848838057915		
8488380RapIDReagentsKD	R8325102	RAPID INOCULATION FLUID 1ML PK/20	RapID 1 mL Inoculation Fluid (R8325102) and RapID 2 mL Inoculation Fluid (R8325106) are accessories for use with RapID identification systems.	848838058547	58208	0363
	R8325106	RAPID INOCULATION FLUID 2ML PK/20		848838058554		

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Basic UDI-DI	Product Code	Product / Trade Name	Intended Use	UDI	GMDN Code	TF #
8488380M4RTA3	SK01360	MICROTEST M4RT (3ML) NPG SWAB KIT, NO BEADS PK/100	MicroTest M4RT (herein referred to as MicroTest M4RT) is a liquid medium recommended for the transport of clinical specimens to the laboratory for microbiological procedures for viral and chlamydial agents. The device is used in a diagnostic workflow to aid clinicians in the treatment options for patients suspected of having viral and bacterial infections.	5032384540259	62392	0404
	SK01361	MICROTEST M4RT (1ML) NPG SWAB KIT, NO BEADS PK/100		5032384540266		

Basic UDI-DI	Product Code	Product / Trade Name	Intended Use	UDI	GMDN Code	TF #
8488380DeminWaterUP	T3339	SENSITITRE DEMINERALIZED WATER	A medium for the dilution of microorganisms isolated from clinical samples for the inoculation of the Sensititre plates as part of the Thermo Scientific™ Sensititre™ System for in vitro antimicrobial susceptibility testing and qualitative identification.	848838011177	58673	0255
	T3339-10			848838020667		
8488380SalTweenGlassB45	T3491	SENSITITRE SALINE - TWEEN WITH GLASS BEADS	A medium for the suspension of microorganisms isolated from clinical samples for the preparation of standardised inoculum to be used with the Sensititre Mycobacterium tuberculosis plates as part of the Thermo Scientific Sensititre System for in vitro antimicrobial susceptibility testing.	848838091322	43674	0468

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