

## EC DECLARATION OF CONFORMITY

The manufacturer declares under its sole responsibility that the products listed below:

<b>Brand Name</b>	<b>SENSITITRE™</b>
<b>Product Group</b>	Microbiology Susceptibility and/or Identification Systems Identification and Susceptibility Plates
<b>Product Codes (GMDN)</b>	<b>63869</b> – MYCOTBI, SLOMYCOI, RAPMYCOI, Gram Negative, Gram Positive and YeastOne <b>50417</b> – GNID <b>50419</b> – GPID
<b>Risk Class</b>	General IVD, non-Annex II and not self-testing devices
<b>Notified Body</b>	<b>BSI</b>

Comply with the essential requirements of the following European Directive:

- **The *in vitro* Diagnostic Medical Devices Directive 98/79/EC**

And comply with the applicable standards:

- EN ISO 13485:2016 (Quality Management Systems)
- EN ISO 14971:2019 (Risk Management)
- CLSI M100S (Performance - Identification and Susceptibility)

<b>PRODUCT CODE</b>	<b>PRODUCT DESCRIPTION</b>
ANAER03	Sensititre Anaerobic
ARGNF	Gram Negative MIC Kit, Plate – Packaged (SIW)
ARGPF	Gram Positive MIC Kit, Plate – Packaged (SIW)
COLCPF	Gram Positive Identification and Susceptibility Plate (SIW)
COLCUNF	Gram Negative Identification and Susceptibility Plates
COLSPM	Gram Positive MIC Plate
COLGN1M	Gram Negative MIC Plate
DKMGN	Sensititre Susceptibility MIC / BP Gram Negative Panel
ESB1F	Sensititre Susceptibility Non-Fastidious ESBL Confirmatory Testing Gram Negative
EUENCF	Sensititre Susceptibility MIC Plate, Gram Positive Panel
EUSTAPF	Sensititre Susceptibility Non-Fastidious Gram Positive MIC Panel
EUXNF	Sensititre Susceptibility MIC Plate Gram Negative Panel
EUGNF	Sensititre Susceptibility Non-Fastidious Gram Negative
EURGNCOL	Sensititre Susceptibility Non-Fastidious Gram Negative
EUX2NF	Sensititre Susceptibility Non-Fastidious Gram Negative
EUMDROF	Sensititre Susceptibility Non-Fastidious Gram Negative
EUMDROXF	Sensititre Susceptibility Non-Fastidious Gram Negative
FRAM1ANA	Sensititre Anaerobic Susceptibility
FR1STENT	Sensititre Susceptibility Non-Fastidious Gram Positive
FRCOL	Sensititre Susceptibility Non-Fastidious Gram Negative
GN2F	Sensititre Susceptibility MIC / BP Gram Negative Panel
GN3F	Sensititre Susceptibility MIC / BP Gram Negative Panel
GN4F	Sensititre Susceptibility MIC / BP Gram Negative Panel
GN6F	Sensititre Susceptibility MIC / BP Gram Negative Panel

**Site Address:** TREK Diagnostic Systems, Limited, (part of Thermo Fisher Scientific)17-19 Birches Industrial Estate, East Grinstead, West Sussex, RH19 1XZ, England – No. 2038515

**Registered Office:** 3<sup>rd</sup> Floor, 1 Ashley Road, Altrincham, Cheshire, WA14 2DT, United Kingdom. Registered in England and Wales – No. 03291857

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GN7F	Sensititre Susceptibility MIC / BP Gram Negative Panel
GNID	Sensititre Gram Negative ID Panel
GNUR2F	Sensititre Susceptibility MIC / BP Gram Negative Panel
GNUR3F	Sensititre Susceptibility MIC / BP Gram Negative Panel
GPALL1F	Sensititre Susceptibility MIC / BP Gram Positive Panel
GPALL3F	Sensititre Susceptibility MIC / BP Gram Positive Panel
GPID	Sensititre Gram Positive ID Panel
GPN3F	Sensititre Susceptibility MIC / BP Gram Positive Panel
HPB1	Sensititre Susceptibility Fastidious Haemophilus Influenzae & Streptococcus pneumoniae.
ITGNEGF	Sensititre Susceptibility Non-Fastidious Gram Negative
ITGPOSF	Sensititre Susceptibility Non-Fastidious Gram Positive
ITHMN	Sensititre Susceptibility Fastidious
ITST4F	Sensititre Susceptibility Fastidious Streptococcus species, Streptococcus pneumoniae.
ITAMYUCC	Sensititre Susceptibility Yeast Isolates.
MYCOTBI	Sensititre Susceptibility Mycobacterium Tuberculosis
MDRGN2F	Sensititre Susceptibility MIC / BP Gram Negative Panel
MEXNC2F	Gram Negative Identification & Susceptibility Kit, Plate-packaged, (SIW)
MEXPC2F	Gram Positive Identification & Susceptibility Kit, Plate-packaged (SIW)
NF	Sensititre Gram Negative MIC Panel
RAPMYCOI	Sensititre Susceptibility Rapid Growing Mycobacterium Nocardia & Other Aerobic Actinomycetes
SLOMYCOI	Sensititre Susceptibility Slow Growing non- Tuberculosis Mycobacterium.
STP6F	Sensititre Susceptibility Fastidious Streptococcus Species
THAN1F	Gram Negative MIC Kit, Plate-Packaged (SIW)
THAN2F	Gram Negative Susceptibility Kit, Plate-packaged (SIW)
THAPF	Gram Positive MIC Kit, Plate-Packaged (SIW)
THAP2F	Gram Positive Susceptibility testing of Staphylococcus and Enterococcus Species
YO2IVD	Sensititre Susceptibility Yeast Isolates.
YO3IVD	Sensititre Susceptibility Yeast Isolates.
YO8	Sensititre Susceptibility Yeast Isolates.
YO10	Sensititre Susceptibility Yeast Isolates.
YO10C	Sensititre Susceptibility Yeast Isolates.

Due to the configurable nature of the Sensititre plate device, it is possible for the customer to specify their own formation of IVD Antimicrobics or Antifungals on to the plate.

The full list of IVD Antimicrobics and Antifungals can be seen below in **Appendix 1**, FDA cleared medicaments **Appendix 2**, a listing of medicaments that are self-declared against performance and stability data for the medicament and or family of medicaments and **Appendix 3** a complete listing of antifungals. The customer may select compatible combinations (microbiological and geographic compatibility) across all lists and this declaration covers those combinations.

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<b>LEGAL MANUFACTURER</b>	<b>EU Authorized Representative</b>
TREK Diagnostic Systems Ltd, (part of Thermo Fisher Scientific) Units 17-19 Birches Industrial Estate East Grinstead West Sussex RH19 1XZ United Kingdom	Thermo Fisher Diagnostics B.V. Scheepbouwersweg 1 B 1121 PC Landsmeer The Netherlands

**QUALITY MANAGEMENT System Certified to ISO13485 standard: BSI MD 719315**

**Expiry Date: 29 April 2021**

**DATE OF VALIDITY:** This declaration is valid for all the IVD medical devices described above which have been placed on the market by TREK on/or after 31<sup>st</sup> October 2019 and which bear the CE marking.

**Signed:** \_\_\_\_\_



**Date: 15 January 2021**

**Name: RISHI DEWAN**

**Position: Senior Regulatory Affairs Specialist**

**Appendix 1**

Antimicrobial	Label Code	Antimicrobial	Label Code
Amikacin	AMI	Erythromycin	ERY
Amoxicillin/Clavulanic Acid	AUG	Fluconazole	FZ
Ampicillin	AMP	Gatifloxacin	GAT
Ampicillin/Sulbactam	A/S	Gemifloxacin	GEM
Azithromycin	AZI	Gentamicin	GEN
Azlocillin	AZL	Grepafloxacin	GRE
Aztreonam	AZT	Imipenem	IMI
Cafazolin	FAZ	Itraconazole	IZ
Carbenicillin	CAR	Kanamycin	KAN
Caspofungin	CAS	Levofloxacin	LEVO
Cefaclor	FAC	Linezolid	LZD
Cefamandole	FAM	Lomefloxacin	LOM
Cefdinir	DIN	Meropenem	MERO
Cefepime	FEP	Methicillin +2%NaCl	MET+
Cefixime	FIX	Mezlocillin	MEZ
Cefonocid	FON	Micafungin	MF
Cefoperazone	FOP	Moxifloxacin	MXF
Cefotaxime	FOT	Nalidixic Acid	NAL
Cefotaxime/Clavulanic Acid	F/C	Netilmicyn	NET
Cefotetan	TANS	Nitrofurantoin	NIT
Cefoxitin	FOX	Norfloxacin	NOR
Cefoxitin screen	FOXs	Ofloxacin	OFL
Cefpodoxime	POD	Oritavancin	ORI
Ceftaroline	CPT	Oxacillin +2% NaCl	OXA+
Ceftaroline	CPT	Penicillin G	PEN
Ceftazidime	TAZ	Piperacillin	PIP
Ceftazidime/ Avibactam	T/N	Piperacillin/Tazobactam	P/T
Ceftazidime/Clavulanic Acid	T/C	Rifampin	RIF
Ceftizoxime	TIZ	Sparfloxacin	SPX
Ceftolozane/Tazobactam	C/T	Streptomycin	STR
Ceftriaxone	AXO	Sulfisoxazole	FIS
Cefuroxime	FUR	Syndercid	SYN
Cephalothin	CEP	Tedizolid	TDZ
Chloramphenicol	CHL	Televancin	TEV
Ciprofloxacin	CIP	Telithromycin	TEL
Clarithromycin	CLA	Tetracycline	TET
Clindamycin	CLI	Ticarcillin	TIM
Dalbavancin	DAL	Tigecycline	TGC
Daptomycin	DAP	Tobramycin	TOB
Doripenem	DOR	Trimethoprim/Sulfamethoxazole	SXT
Doxycycline	DOX	Trovafloxacin	TVA
DTEST	DT1/DT2	Vancomycin	VAN
Ertapenem	ERT	Voriconazole	VOR
Ertapenem	ETP	5-Flucytosine	FC

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**Appendix 2**

Antimicrobial	Label Code	Antimicrobial	Label Code
Apramycin	APR	Moxalactam	MOX
Bacitracin	BAC	Mupirocin	MUP
Cefprozil	CPZ	Neomycin	NEO
Cefquinome	CQN	Novobiocin	NOV
Ceftibuten	TIB	Orbifloxacin	ORB
Ceftriaxone/Clavulanic Acid	X/C	Oxolonic Acid	OXO
Cephalexin	LEX	Oxytetracycline	OXY
Cephapirin	HAP	Penicillin/Novobiocin	P/N
Cephradine	RAD	Pipemidic Acid	PA
Chlortetracycline	CTET	Polymixin B	POL
Cinoxacin	CIN	Spectinomycin	SPE
Cloxacillin	CLO	Sulphachloropyridazine	SCP
Colistin	COL	Sulphadimethoxine	SDM
Difloxacin	DIF	Sulphadimethoxine/Ormetoprim	PRI
Florfenicol	FFN	Sulphadimidine	SDI
Fosfomycin +G-6-P	FOS+	Sulphamethoxazole	SMX
Fusidate	FUS	Sulphathiazole	STZ
Garenoxacin	GRN	Teicoplanin	TEI
Ibafloxacin	IBA	Trimethoprim	TMP
Lincomycin	LIN	Trimethoprim/Sulphadiazine	TBR

**Appendix 3**

<b>Antimicrobial</b>	<b>Label Code</b>
Amphotericin B	AB
Amphotericin B with alamarBlue®	AB
Anidulafungin	AND
Anidulafungin with alamar Blue	AND
Caspofungin with alamarBlue®	CAS
5-Flucytosine	FC
5-Flucytosine with alamarBlue®	FC
Fluconazole	FZ
Fluconazole with alamarBlue®	FZ
Isavuconazole	ISA
Isavuconazole with alamar Blue	ISA
Itraconazole	IZ
Itraconazole with alamarBlue®	IZ
Ketoconazole	KZ
Ketoconazole with alamarBlue®	KZ
Micafungin	MF
Micafungin with alamarBlue®	MF
Posaconazole + alamarBlue®	PZ
Ravuconazole + alamarBlue®	RZ
Voriconazole	VOR
Voriconazole with alamarBlue®	VOR