

## EC DECLARATION OF CONFORMITY

I, the undersigned, hereby declare that the in vitro diagnostic devices described below conform to all the applicable essential requirements contained in Annex I *Essential Requirement* and Annex III –*Declaration of Conformity of the In Vitro Diagnostic Devices Directive 98/79/EC*.

These products are self declared via Annex III of the IVDD. This conformance is supported by the technical documentation which is maintained by TREK Diagnostic Systems Ltd.

PRODUCT CODE	PRODUCT DESCRIPTION
V4007	Sensititre Manual Viewer
V3011	Sensititre Nephelometer
E3010	Sensititre Dosing heads
V3020	Sensititre Aim
V2021	Sensititre Vizion
V3030	Sensititre OptiRead
MINOIL	Sensititre Mineral Oil

Note - See Appendix 4

PRODUCT CODE	PRODUCT DESCRIPTION
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
GN2F	Sensititre Susceptibility MIC/ BP Gram Negative Panel
GN3F	Sensititre Susceptibility MIC/ BP Gram Negative Panel
GN4F	Sensititre Susceptibility MIC/ BP Gram Negative Panel
GNID	Sensititre Gram Negative ID Panel
GNUR2F	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.
MYCOTBI	Sensititre Susceptibility Mycobacterium Tuberculosis
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
YO10	Sensititre Susceptibility Yeast Isolates.
YO2IVD	Sensititre Susceptibility Yeast Isolates.
YO8	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 (Antifungals in **bold**), **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.

**MANUFACTURER / EU REP:**

TREK Diagnostic Systems Ltd,  
part of Thermo Fisher Scientific  
Units 17-19 Birches Industrial Estate  
East Grinstead  
West Sussex  
RH19 1XZ  
United Kingdom

**QUALITY MANAGEMENT System Certified to ISO13485 standard: LRQA 0962758**

**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 28<sup>th</sup> November 2003 and which bear the CE marking.

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

Date: 06<sup>th</sup> March 2017

Name: Phil Brame

Position: Senior Regulatory Affairs Officer

**Appendix 1**

Antimicrobial	Label Code	Antimicrobial	Label Code
Amikacin	AMI	Erythromycin	ERY
Amoxicillin/Clavulanic Acid	AUG	<b>Fluconazole</b>	<b>FZ</b>
Ampicillin	AMP	Gatifloxacin	GAT
Ampicillin/Sulbactam	A/S	Gemifloxacin	GEM
Azithromycin	AZI	Gentamicin	GEN
Azlocillin	AZL	Grepafloracin	GRE
Aztreonam	AZT	Imipenem	IMI
Cafazolin	FAZ	<b>Itraconazole</b>	<b>IZ</b>
Carbenicillin	CAR	Kanamycin	KAN
<b>Caspofungin</b>	<b>CAS</b>	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	<b>Micafungin</b>	<b>MF</b>
Cefoperazone	FOP	Moxifloxacin	MXF
Cefotaxime	FOT	Nalidixic Acid	NAL
Cefotaxime/Clavulanic Acid	F/C	Netilmicin	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	Ticarillin	TIM
Dalbavancin	DAL	Tigecycline	TGC
Daptomycin	DAP	Tobramycin	TOB
Doripenem	DOR	Trimethoprim/Sulfamethoxazole	SXT
Doxycycline	DOX	Trovafloracin	TVA
DTEST	DT1/DT2	Vancomycin	VAN
Ertapenem	ERT	<b>Voriconazole</b>	<b>VOR</b>
Ertapenem	ETP	<b>5-Flucytosine</b>	<b>FC</b>

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

\* **Appendix 4**

Withdrawn Items.

The following items have been withdrawn from this declaration as they have been found to require remediation for RoHS 2 compliance.

These items will be returned to this declaration as compliant on completion of the remediation of this deficiency.

<i>Product Code</i>	<i>Product Description</i>	<i>Estimated Completion</i>
V3090 *	Sensititre Aris	2018 (as updated instrument)