



EU Declaration of Conformity

Name of Device / Product Group	SENSITITRE™
Product Description	Microbiology Susceptibility and/or Identification Systems Identification and Susceptibility Plates
Product Code / Product and Trade Name	See attached product schedule
 Legal Manufacturer	TREK Diagnostic Systems Limited, 17-19 Birches Industrial Estate, East Grinstead, West Sussex, RH19 1XZ, UK
 European Authorized Representative	Thermo Fisher Diagnostics B.V. Scheepsbouwersweg 1 B, 1121 PC Landsmeer, NL
Risk Class	Self-Declared – Non-Annex II Products and Not Self-Test Devices
Conformity Route	Annex III

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 EC Directive 98/79/EC concerning In Vitro Diagnostic Medical Devices (IVDD).

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

This declaration is supported by the Quality Management System which is certified to EN ISO 13485:2016 Standard (BSI Certificate no. MD 719315).

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.

Signature:



Digitally signed by
Desmond Miles
Date: 2022.05.17
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Name:

Function: Regulatory Affairs

Issued in: United Kingdom

Product Schedule

The products related to EU DOC - Sensititre Plates Standard (Rev 1) are listed below:

Product Code	Product and Trade Name	GMDN Code
ANAERO3	SENSITITRE ANAEROBIC	63869
DKMGN	SENSITITRE SUSCEPTIBILITY MIC / BP GRAM NEGATIVE PANEL	63869
ESB1F	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS ESBL CONFIRMATORY TESTING GRAM NEGATIVE	63869
EUENCF	SENSITITRE SUSCEPTIBILITY MIC PLATE, GRAM POSITIVE PANEL	63869
EUMDRXXF	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS GRAM NEGATIVE	63869
EUSTAPF	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS GRAM POSITIVE MIC PANEL	63869
EUXNF	SENSITITRE SUSCEPTIBILITY MIC PLATE GRAM NEGATIVE PANEL	63869
EUGNF	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS GRAM NEGATIVE	63869
EURGNCOL	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS GRAM NEGATIVE	63869
EUX2NF	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS GRAM NEGATIVE	63869
EUMDROF	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS GRAM NEGATIVE	63869
EUMDROXF	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS GRAM NEGATIVE	63869
FDANDPF	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS GRAM NEGATIVE AND GRAM-POSITIVE ISOLATES	63869
FDANDSF	SENSITITRE SUSCEPTIBILITY FASTIDIOUS STREPTOCOCCUS PNEUMONIA	63869
FR1STENT	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS GRAM POSITIVE	63869
FRCOL	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS GRAM NEGATIVE	63869
GN2F	SENSITITRE SUSCEPTIBILITY MIC / BP GRAM NEGATIVE PANEL	63869
GN3F	SENSITITRE SUSCEPTIBILITY MIC / BP GRAM NEGATIVE PANEL	63869
GN4F	SENSITITRE SUSCEPTIBILITY MIC / BP GRAM NEGATIVE PANEL	63869
GN6F	SENSITITRE SUSCEPTIBILITY MIC / BP GRAM NEGATIVE PANEL	63869
GN7F	SENSITITRE SUSCEPTIBILITY MIC / BP GRAM NEGATIVE PANEL	63869
GNID	SENSITITRE GRAM NEGATIVE ID PANEL	50417
GNUR2F	SENSITITRE SUSCEPTIBILITY MIC / BP GRAM NEGATIVE PANEL	63869
GNUR3F	SENSITITRE SUSCEPTIBILITY MIC / BP GRAM NEGATIVE PANEL	63869
GPALL1F	SENSITITRE SUSCEPTIBILITY MIC / BP GRAM POSITIVE PANEL	63869
GPALL3F	SENSITITRE SUSCEPTIBILITY MIC / BP GRAM POSITIVE PANEL	63869
GPID	SENSITITRE GRAM POSITIVE ID PANEL	50419
GPN3F	SENSITITRE SUSCEPTIBILITY MIC / BP GRAM POSITIVE PANEL	63869

Product Code	Product and Trade Name	GMDN Code
HPB1	SENSITITRE SUSCEPTIBILITY FASTIDIOUS HAEMOPHILUS INFLUENZAE & STREPTOCOCCUS PNEUMONIAE.	63869
ITAMYUCC	SENSITITRE SUSCEPTIBILITY YEAST ISOLATES	63869
MYCOTBI	SENSITITRE SUSCEPTIBILITY MYCOBACTERIUM TUBERCULOSIS	63870
MDRGN2F	SENSITITRE SUSCEPTIBILITY MIC/BP GRAM NEGATIVE PANEL	63869
NF	SENSITITRE GRAM NEGATIVE MIC PANEL	63869
RAPMYCOI	SENSITITRE SUSCEPTIBILITY RAPID GROWING MYCOBACTERIUM NOCARDIA & OTHER AEROBIC ACTINOMYCETES	63870
SLOMYCOI	SENSITITRE SUSCEPTIBILITY SLOW GROWING NON-TUBERCULOSIS MYCOBACTERIUM	63870
STP6F	SENSITITRE SUSCEPTIBILITY FASTIDIOUS STREPTOCOCCUS SPECIES	63869
YO2IVD	SENSITITRE SUSCEPTIBILITY YEAST ISOLATES.	63870
YO3IVD	SENSITITRE SUSCEPTIBILITY YEAST ISOLATES.	63870
YO8	SENSITITRE SUSCEPTIBILITY YEAST ISOLATES.	63870
YO10	SENSITITRE SUSCEPTIBILITY YEAST ISOLATES.	63870

Appendix 1

The IVD Antimicrobics and Antifungals related to EU DOC - Sensititre Plates Standard (Rev 1) are listed below:

Antimicrobial	Label Code	Antimicrobial	Label Code
AMIKACIN	AMI	ERYTHROMYCIN	ERY
AMOXYCILLIN/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

Antimicrobial	Label Code	Antimicrobial	Label Code
CEFTOLOZANE/TAZOBACTAM	C/T	STREPTOMYCIN	STR
CEFTRIAZONE	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

Appendix 2

The FDA cleared medicaments related to EU DOC - Sensititre Plates Standard (Rev 1) are listed below:

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
CEFTRIAZONE/CLAVULANIC ACID	X/C	OXOLONIC ACID	OXO
CEPHALEXIN	LEX	OXYTETRACYCLINE	OXY
CEPHAPIRIN	HAP	PENICILLIN/NOVOBIOCIN	P/N
CEPHRADINE	RAD	PIPEMIDIC ACID	PA
CHLORTETRACYCLINE	CTET	POLYMXIN 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

The FDA cleared medicaments related to EU DOC - Sensititre Plates Standard (Rev 1) are listed below:

Antimicrobial	Label Code	Antimicrobial	Label Code
AMPHOTERICIN B	AB	ITRACONAZOLE	IZ
AMPHOTERICIN B WITH ALAMARBLUE®	AB	ITRACONAZOLE WITH ALAMARBLUE®	IZ
ANIDULAFUNGIN	AND	KETOCONAZOLE	KZ
ANIDULAFUNGIN WITH ALAMAR BLUE	AND	KETOCONAZOLE WITH ALAMARBLUE®	KZ
CASPOFUNGIN WITH ALAMARBLUE®	CAS	MICAFUNGIN	MF
5-FLUCYTOSINE	FC	MICAFUNGIN WITH ALAMARBLUE®	MF
5-FLUCYTOSINE WITH ALAMARBLUE®	FC	POSACONAZOLE + ALAMARBLUE®	PZ
FLUCONAZOLE	FZ	RAVUCONAZOLE + ALAMARBLUE®	RZ
FLUCONAZOLE WITH ALAMARBLUE®	FZ	VORICONAZOLE	VOR
ISAVUCONAZOLE	ISA	VORICONAZOLE WITH ALAMARBLUE®	VOR
ISAVUCONAZOLE WITH ALAMAR BLUE	ISA		