

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		
<table border="1"><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
EC	REP		
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. 719315).

Signature:

Name:

Function: Regulatory Affairs

Issued in: United Kingdom

Product Schedule

The products related to EU DOC - Customer Specified Plates (Rev 7) are listed below:

Product Code	Product and Trade Name	GMDN Code
ARGNF	GRAM NEGATIVE MIC KIT, PLATE - PACKAGED (SIW)	63869
ARGPF	GRAM POSITIVE MIC KIT, PLATE - PACKAGED (SIW)	63869
CHE2HUG	PLATE DRY CUSTOM IVD GRAM NEG	63869
COLCPF	GRAM POSTIVE IDENTIFICATION AND SUSCEPTIBILITY PLATE (SIW)	63869
COLCUNF	GRAM NEGATIVE IDENTIFICATION AND SUSCEPTIBILITY PLATES	63869
COLSPM	GRAM POSITIVE MIC PLATE	63869
COLGN1M	GRAM NEGATIVE MIC PLATE	63869
BEGN4A	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS GRAM NEGATIVE	63869
BEGN4B	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS GRAM NEGATIVE	63869
BEGNUZ	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS GRAM NEGATIVE	63869
BEGNUZ2	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS GRAM NEGATIVE	63869
BELKUL1	SENSITITRE SUSCEPTIBILITY FASTIDIOUS STREPTOCOCCUS PNEUMONIA MIC SUSCEPTIBILITY PANEL	63869
BEGNUZ3	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS GRAM NEGATIVE	63869
BELGN3	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS GRAM NEGATIVE	63869
BELSSSP1	SENSITITRE SUSCEPTIBILITY FASTIDIOUS STREPTOCOCCUS PNEUMONIA	63869
BELWIV	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS GRAM NEGATIVE	63869
BEMST5	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS GRAM POSITIVE	63869
BEMST6	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS STAPHYLOCOCCUS SPECIES	63869
BENRC	SENSITITRE SUSCEPTIBILITY FASTIDIOUS STREPTOCOCCUS PNEUMONIA	63869
BENRC2	SENSITITRE SUSCEPTIBILITY FASTIDIOUS STREPTOCOCCUS SPECIES	63869
CHE2HUG	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS GRAM NEGATIVE	63869
CHE1GNCC	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS GRAM NEGATIVE AND GRAM POSITIVE	63869
CHE1USB	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS STAPHYLOCOCCUS SPECIES	63869
DEUBCN1	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS GRAM NEGATIVE	63869
DEUGNGOE	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS GRAM NEGATIVE	63869
DEUGNGOF	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS GRAM NEGATIVE	63869

Product Code	Product and Trade Name	GMDN Code
DEUPGO1F	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS GRAM POSITIVE	63869
DEUUGO1F	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS GRAM NEGATIVE	63869
DEU1GANA	SENSITITRE SUSCEPTIBILITY ANAEROBIC ISOLATES	63869
DEU1FPGN	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS PSEUDOMONAS SPECIES	63869
DEUAGO1F	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS GRAM NEGATIVE	63869
DEUSGO1F	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS STAPHYLOCOCCUS SPECIES	63869
DEUGNG2F	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS GRAM NEGATIVE	63869
DKMGNF	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS GRAM NEGATIVE	63869
ESPUGMA2	SENSITITRE SUSCEPTIBILITY ANAEROBIC ISOLATES	63869
EUMDRXXF	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS GRAM NEGATIVE	63869
ESTEN2F	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS GRAM POSITIVE	63869
FDANDPF	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS GRAM NEGATIVE AND GRAM-POSITIVE ISOLATES	63869
FDANDSF	SENSITITRE SUSCEPTIBILITY FASTIDIOUS STREPTOCOCCUS PNEUMONIA	63869
FRAM1GN	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS GRAM NEGATIVE	63869
FRAM2GN	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS GRAM NEGATIVE	63869
FRAMSPC2	SENSITITRE SUSCEPTIBILITY HAEMOPHILUS INFLUENZAE / STREPTOCOCCUS PNEUMONIA MIC SUSCEPTIBILITY PANEL	63869
FRCERGP1	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS GRAM POSITIVE	63869
FRHCLST2	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS STAPHYLOCOCCUS SPECIES	63869
FRMDRO1	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS GRAM NEGATIVE	63869
FINRGP1	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS GRAM POSITIVE	63869
FRPNEUM2	SENSITITRE SUSCEPTIBILITY FASTIDIOUS STREPTOCOCCUS PNEUMONIA	63869
FRUNIGN1	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS GRAM NEGATIVE	63869
FRUNIGP1	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS GRAM POSITIVE	63869
FR2STENT	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS GRAM POSITIVE	63869
FRCERGN1	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS GRAM NEGATIVE	63869
FRHSL1F	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS PSEUDOMONAS SPECIES	63869
FRAM1ANA	SENSITITRE ANAEROBIC (ROW)	63869

Product Code	Product and Trade Name	GMDN Code
GB1ODX	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS GRAM NEGATIVE & NON-FASTIDIOUS GRAM POSITIVES	63869
GBHCAS1F	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS STAPHYLOCOCCUS SPECIES	63869
GBHCAN1F	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS GRAM-NEGATIVE ISOLATES	63869
GBHCAR1F	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS GRAM-NEGATIVE ISOLATES	63869
GBHCAU1F	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS GRAM-NEGATIVE ISOLATES	63869
GBHCAE1F	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS ENTEROCOCCUS SPECIES	63869
GBUHWGN1	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS ENTEROBACTERALES AND PSEUDOMONAS AERUGINOSA	63869
HKG1GNF	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS GRAM NEGATIVE	63869
HK1MHKAF	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS GRAM NEGATIVE	63869
HK2MHKBF	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS GRAM POSITIVE	63869
HK3MHKF	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS GRAM NEGATIVE	63869
IRN5F	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS ENTEROBACTERALES	63869
ITNIGGN1	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS ENTEROBACTERALES AND NON-FERMENTERS	63869
IRBP11F	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS STAPHYLOCOCCUS SPECIES	63869
IRE2SSP	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS STAPHYLOCOCCUS SPECIES	63869
ITGNEGF	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS GRAM NEGATIVE	63869
ITGPOSF	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS GRAM POSITIVE	63869
ITHMN	SENSITITRE SUSCEPTIBILITY FASTIDIOUS	63869
ITST4F	SENSITITRE SUSCEPTIBILITY FASTIDIOUS STREPTOCOCCUS SPECIES, STREPTOCOCCUS PNEUMONIAE.	63869
JORCNF	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS GRAM NEGATIVE	63869
LUXMDR1F	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS GRAM NEGATIVE	63869
LUXHSS1	SENSITITRE SUSCEPTIBILITY FASTIDIOUS HAEMOPHILUS SPECIES AND STREPTOCOCCUS SPECIES	63869
MEXNC2F	GRAM NEGATIVE IDENTIFICATION & SUSCEPTIBILITY KIT, PLATE-PACKAGED (SIW)	63869

Product Code	Product and Trade Name	GMDN Code
MEXPC2F	GRAM POSITIVE IDENTIFICATION & SUSCEPTIBILITY KIT, PLATE-PACKAGED (SIW)	63869
MLTENT1F	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS GRAM-POSITIVE ISOLATES	63869
MLTGN1F	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS GRAM-NEGATIVE ISOLATES	63869
MLTGN2F	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS GRAM-NEGATIVE ISOLATES	63869
MLTSTA1F	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS STREPTOCOCCUS SPECIES	63869
MLTSTR1F	SENSITITRE SUSCEPTIBILITY FASTIDIOUS STREPTOCOCCUS SPECIES	63869
NONAG8	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS ENTEROBACTEREALES	63869
NONAG8X	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS GRAM NEGATIVE	63869
NONAG9	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS ENTEROBACTEREALES	63869
POLGNU1F	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS GRAM NEGATIVE	63869
POLGNA1F	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS GRAM NEGATIVE	63869
POLGNK1F	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS GRAM NEGATIVE	63869
RUNBF	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS GRAM NEGATIVE	63869
RUNAF	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS GRAM NEGATIVE	63869
RUSTEF	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS GRAM POSITIVE	63869
RUSEN1F	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS GRAM NEGATIVE	63869
RUSUR3IF	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS GRAM NEGATIVE	63869
RUSYGN1F	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS GRAM NEGATIVE	63869
SEMEDL	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS GRAM NEGATIVE	63869
SEMSE7	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS GRAM POSITIVE	63869
SEMHI2	SENSITITRE SUSCEPTIBILITY FASTIDIOUS STREPTOCOCCUS AND HAEMOPHILUS SPECIES	63869
SGMDRO1F	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS GRAM NEGATIVE	63869
STRHAE2	SENSITITRE SUSCEPTIBILITY HAEMOPHILUS INFLUENZAE / STREPTOCOCCUS PNEUMONIA	63869
SWE1PHAS	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS GRAM NEGATIVE	63869
SWE1STAA	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS GRAM POSITIVE	63869
SWE2ESB	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS GRAM NEGATIVE	63869
THAN1F	GRAM NEGATIVE MIC KIT, PLATE - PACKAGED (SIW)	63869

Product Code	Product and Trade Name	GMDN Code
THAN2F	GRAM NEGATIVE SUSCEPTIBILITY KIT, PLATE - PACKAGED (SIW)	63869
THAPF	GRAM POSITIVE MIC KIT, PLATE - PACKAGED (SIW)	63869
THAP2F	GRAM POSITIVE SUSEPTIBILITY TESTING OF STAPHYLOCOCCUS AND ENTEROCOCCUS SPECIES	63869
YO10C	SENSITITRE SUSCEPTIBILITY YEAST ISOLATES.	63870
ZA1CRE	SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS ENTEROBACTERALES	63869