

## EU Declaration of Conformity

|                                                                                                                                   |                                                                                                                   |     |                                                                                |
|-----------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------|-----|--------------------------------------------------------------------------------|
| Name of Device / Product Group                                                                                                    | <b>SENSITITRE™</b>                                                                                                |     |                                                                                |
| Product Description                                                                                                               | Microbiology Susceptibility and/or Identification Systems<br>Identification and Susceptibility Plates             |     |                                                                                |
| Product Code / Product and Trade Name                                                                                             | See attached product schedule                                                                                     |     |                                                                                |
| <br>Legal Manufacturer                           | TREK Diagnostic Systems Limited,<br>17-19 Birches Industrial Estate, East Grinstead,<br>West Sussex, RH19 1XZ, UK |     |                                                                                |
| <table border="1" data-bbox="130 795 327 851"> <tr> <td>EC</td> <td>REP</td> </tr> </table><br>European Authorized Representative | EC                                                                                                                | REP | Thermo Fisher Diagnostics B.V.<br>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 SUSECPTIBILITY TESTING OF STAPHYLOCOCCUS AND ENTEROCOCCUS SPECIES | 63869     |
| YO10C        | SENSITITRE SUSCEPTIBILITY YEAST ISOLATES.                                       | 63870     |
| ZA1CRE       | SENSITITRE SUSCEPTIBILITY NON-FASTIDIOUS ENTEROBACTERALES                       | 63869     |