

## EC DECLARATION OF CONFORMITY

|                               |  |  |
|-------------------------------|--|--|
| <b>Manufacturer:</b>          | Becton, Dickinson and Company<br>Belliver Industrial Estate, Belliver Way, Roborough, Plymouth,<br>PL6 7BP, United Kingdom |  |
| <b>Manufacturing Site(s):</b> | Becton, Dickinson and Company<br>Belliver Industrial Estate, Belliver Way, Roborough, Plymouth,<br>PL6 7BP, United Kingdom |  |
| <b>Products:</b>              | <b>Catalogue number</b>  | <b>Device name</b>   |
|                               | 362074   | BD Vacutainer® SST™ II Advance Plus Blood Collection Tubes |
|                               | 362075   | BD Vacutainer® SST™ II Advance Plus Blood Collection Tubes |
|                               | 362076   | BD Vacutainer® SST™ II Advance Plus Blood Collection Tubes |
|                               | 362077   | BD Vacutainer® SST™ II Advance Plus Blood Collection Tubes |
|                               | 362078   | BD Vacutainer® SST™ II Advance Plus Blood Collection Tubes |
|                               | 362079   | BD Vacutainer® SST™ II Advance Plus Blood Collection Tubes |
|                               | 362090   | BD Vacutainer® SST™ II Advance Plus Blood Collection Tubes |
|                               | 365301   | BD Vacutainer® SST™ II Advance Plus Blood Collection Tubes |
|                               | 365302   | BD Vacutainer® SST™ II Advance Plus Blood Collection Tubes |
|                               | 365317   | BD Vacutainer® SST™ II Advance Plus Blood Collection Tubes |
|                               | 365327   | BD Vacutainer® SST™ II Advance Plus Blood Collection Tubes |
|                               | 365328   | BD Vacutainer® SST™ II Advance Plus Blood Collection Tubes |
|                               | 366127   | BD Vacutainer® SST™ II Advance Plus Blood Collection Tubes |
|                               | 366444   | BD Vacutainer® SST™ II Advance Plus Blood Collection Tubes |
|                               | 366468   | BD Vacutainer® SST™ II Advance Plus Blood Collection Tubes |
|                               | 366566   | BD Vacutainer® SST™ II Advance Plus Blood Collection Tubes |
|                               | 366644   | BD Vacutainer® SST™ II Advance Plus Blood Collection Tubes |
|                               | 366880   | BD Vacutainer® SST™ II Advance Plus Blood Collection Tubes |
|                               | 366881   | BD Vacutainer® SST™ II Advance Plus Blood Collection Tubes |
|                               | 366882   | BD Vacutainer® SST™ II Advance Plus Blood Collection Tubes |
|                               | 367953   | BD Vacutainer® SST™ II Advance Plus Blood Collection Tubes |
|                               | 367954   | BD Vacutainer® SST™ II Advance Plus Blood Collection Tubes |
|                               | 367955   | BD Vacutainer® SST™ II Advance Plus Blood Collection Tubes |
|                               | 367956   | BD Vacutainer® SST™ II Advance Plus Blood Collection Tubes |
|                               | 367957   | BD Vacutainer® SST™ II Advance Plus Blood Collection Tubes |
|                               | 367958   | BD Vacutainer® SST™ II Advance Plus Blood Collection Tubes |
|                               | 368498   | BD Vacutainer® SST™ II Advance Plus Blood Collection Tubes |
|                               | 368879   | BD Vacutainer® SST™ II Advance Plus Blood Collection Tubes |
|                               | 368965   | BD Vacutainer® SST™ II Advance Plus Blood Collection Tubes |
|                               | 368966   | BD Vacutainer® SST™ II Advance Plus Blood Collection Tubes |
|                               | 368967   | BD Vacutainer® SST™ II Advance Plus Blood Collection Tubes |
|                               | 368968   | BD Vacutainer® SST™ II Advance Plus Blood Collection Tubes |
|                               | 368969   | BD Vacutainer® SST™ II Advance Plus Blood Collection Tubes |
|                               | 368970   | BD Vacutainer® SST™ II Advance Plus Blood Collection Tubes |
|                               | 36795306   | BD Vacutainer® SST™ II Advance Plus Blood Collection Tubes |
| <b>IVDD Classification:</b>   | Non Annex II <i>In Vitro</i> Diagnostic Medical Device   |  |

|  |                                   |
|--|-----------------------------------|
| <b>IVDD Conformity Assessment Route:</b> | Annex III (excluding Annex III.6) |
| <b>GMDN:</b>                             | 41128                             |

We herewith declare that the above mentioned products meet the provisions of the Council Directive 98/79/EC for *in vitro* diagnostic medical devices. This declaration is based on conformity to Annex III (excluding Annex III.6). All supporting documentation is retained under the premises of the manufacturer.

**List of Harmonized Standards:**

**EN ISO 13485:2012** Medical devices — Quality management systems — Requirements for regulatory purposes **EN ISO 14971:2012** Medical Devices – Application of risk management to medical devices **EN 556-1:2001** Sterilisation of medical devices – Requirements for medical devices to be designated “STERILE” – Part 1: Requirements for terminally sterilized medical devices **EN ISO 11137-1:2015** Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices **EN ISO 11137-2:2015** Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose. **EN ISO 11737-2:2009** Sterilization of medical devices - Microbiological methods Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process **EN 14820:2004** Single-use containers for human venous blood specimen collection **EN 62366:2008** Medical devices - Application of usability engineering to medical devices **EN ISO 18113-1: 2011** In vitro diagnostic medical devices – Information supplied by the manufacturer (Labelling). Part 1: Terms, definitions and general requirements (ISO 18113-1:2009) **EN ISO 18113-2: 2011** In vitro diagnostic medical devices – Information supplied by the manufacturer (Labelling). Part 2: In vitro diagnostic reagents for professional use (ISO 18113-2:2009) **EN ISO 15223-1:2016** Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements

**List of Non-Harmonised Standards:**

**ISO 14001:2015** Environmental management systems - Requirements with guidance for use **EN ISO 11137-3:2017** Sterilisation of health care product – Radiation – part 3: guidance on dosimetric aspects of development, validation and routine control **EN ISO 11737-1:2018** Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products **ISO 6710:1995** Single-Use Containers for Venous Blood Specimen Collection **EN ISO 14698-1:2003** Cleanrooms and associated controlled environments – Biocontamination control — Part 1: General principles and methods **EN ISO 14698-2:2003** Cleanrooms and associated controlled environments -- Biocontamination control — Part 2: Evaluation and interpretation of biocontamination data **EN ISO 14644-1:2015** Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness **EN ISO 14644-2:2015** Cleanrooms and associated controlled environments -- Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration **ISO 2859-1:1999** Sampling procedures for inspection by attributes - Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection **ASTM D5276:1998 (R 2009)** Standard Test Method for Drop Test of Loaded Containers by Free Fall **ASTM D999: 2008 (R2015)** Standard Test Methods for Vibration Testing of Shipping Containers **ASTM D4169: 2014** Standard Practice for Performance Testing of Shipping Containers and Systems **ASTM D4728: 2006 (R2012)** Standard Test Method for Random Vibration Testing of Shipping Containers **ASTM D-775: 1980 (R 1986)** Standard Test Method for Drop Test for Loaded Boxes

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SIGNED FOR AND ON BEHALF OF: Becton, Dickinson and Company

PLACE, DATE OF ISSUE: Plymouth, 18<sup>th</sup> September 2018

Signature: 

Brad Spring

Vice President, Regulatory Affairs

BD Life Sciences

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### VERSION HISTORY

Current Version Prepared By: Joseph Statham

| <b>REV.</b> | <b>Version Description</b>  |
|-------------|---|
| A           | Transferred from QDMS to ECC – Version number remained  |
| B           | Transfer into new IVD Declaration of Conformity Template (MED-RA-001D). Addition of 36795306 as per ACR PAS-000561. |
| C           | Update to harmonised and non-harmonised standards.  |
| D           | Update EN ISO 11737-1:2006 to EN ISO 11737-1:2018 as per CAPA 325553.   |