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EC DECLARATION OF CONFORMITY

Manufacturer:	Becton, Dickinson and Company Belliver Industrial Estate, Belliver Way, Roborough, Plymouth, PL6 7BP, United Kingdom
Manufacturing Site(s):	Becton, Dickinson and Company Belliver Industrial Estate, Belliver Way, Roborough, Plymouth, PL6 7BP, United Kingdom
Products:	**Catalogue number** — **Device name** 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
IVDD Classification:	Non Annex II *In Vitro* Diagnostic Medical Device

Registered Office: Becton Dickinson UK Ltd. 1030 Eskdale Road, Wokingham, Berkshire, RG41 5TS. UK.
Registered No. 852702

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IVDD Conformity Assessment Route:	Annex III (excluding Annex III.6)
GMDN:	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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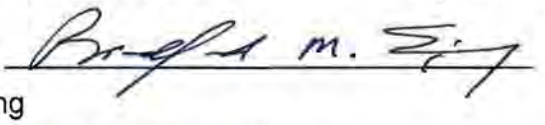
SIGNED FOR AND ON BEHALF OF: Becton, Dickinson and Company

PLACE, DATE OF ISSUE: Plymouth, 18th September 2018

Signature: 

Brad Spring
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Document Number: VR4310020

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VERSION HISTORY

Current Version Prepared By: Joseph Statham

REV.	Version Description
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.