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Document Number: VR4310020

# EC DECLARATION OF CONFORMITY

## Document No.: VR4310020

| | |
|---|---|
| **Manufacturer:** | Becton, Dickinson and Company<br>Belliver Industrial Estate, Belliver Way, Roborough, Plymouth,<br>PL6 7BP, United Kingdom |
| **Authorized Representative:** | BD-Switzerland Sàrl<br>Terre Bonne Park-A4<br>Route de Crassier 17<br>1262 Eysins<br>Switzerland |
| **Manufacturing Site(s):** | Becton, Dickinson and Company<br>Belliver Industrial Estate, Belliver Way, Roborough, Plymouth,<br>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 |
| 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 |
| F-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 |

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| | | |
|---|---|---|
| | 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 |
| | 360078 | BD Vacutainer® SST™ II Advance Plus Blood Collection Tubes |
| | 360079 | BD Vacutainer® SST™ II Advance Plus Blood Collection Tubes |
| | 360080 | BD Vacutainer® SST™ II Advance Plus Blood Collection Tubes |
| | 366883 | BD Vacutainer® SST™ II Advance Plus Blood Collection Tubes |
| | 366451 | BD Vacutainer® SST™ II Advance Plus Blood Collection Tubes |
| **IVDD Classification:** | Non Annex II *In Vitro* Diagnostic Medical Device | |
| **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 13485:2016** 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. **BS EN ISO 11737-2:2020** 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**

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**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

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

DATE OF ISSUE: 18-September-2020

**Signature:**

Kay Taylor
Vice President, Regulatory Affairs
Life Science and IDS

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## VERSION HISTORY

Current Version Prepared By: S. Chaudhry

| 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. |
| E | Added catalog number F-367955 as per ACR PAS-2019-0021-00 "Repacking of SKUs as per tender requirements in Norway". |
| F | Obsoleted CAT No. 365317 per ACR PAS 000671-00. Updated ISO 13485-2012 to 2016. |
| G | Added Authorized Rep: BD Switzerland |
| H | Added new catalog numbers, 360078, 360079, 360080 for prebarcoded product requested by European marketing, ACR PAS-2019-0075 Serialization of Product on Unit Level with Barcode (Universal Specimen Identification – USI). |
| I | Changed reference from EN ISO 11737-2:2009 to BS EN ISO 11737-2:2020 per BDVS-2020-04-29-113742. Added new catalog numbers for prebarcoded product requested by European marketing, ACR PAS-2019-0075 Serialization of Product on Unit Level with Barcode (Universal Specimen Identification – USI), 366883 & 366451. Updated to BD IDS-SM. |