EC DECLARATION OF CONFORMITY

Document Number: VR4310009

Manufacturer:	Becton, Dickinson and Company Belliver Industrial Estate, Belliver Way, Roborough, Plymouth, PL6 7BP, United Kingdom
Authorized Representative:	BD-Switzerland Sàrl Terre Bonne Park-A4 Route de Crassier 17 1262 Eysins Switzerland
Manufacturing Site(s):	Becton, Dickinson and Company Belliver Industrial Estate, Belliver Way, Roborough, Plymouth, PL6 7BP, United Kingdom *Becton Dickinson and Company 150 South First Avenue, Broken Bow, NE, 68822, USA
Products:	**Catalogue number** — **Device name** 363047 — BD Vacutainer® 9NC 0.109M Buffered Trisodium Citrate Plus Blood Collection Tubes 363048 — BD Vacutainer® 9NC 0.109M Buffered Trisodium Citrate Plus Blood Collection Tubes 363079 — BD Vacutainer® 9NC 0.129M Plus Blood Collection Tubes 363093 — BD Vacutainer® 9NC 0.109M Plus Blood Collection Tubes 363095 — BD Vacutainer® 9NC 0.109M Plus Blood Collection Tubes 363097 — BD Vacutainer® 9NC 0.129M Plus Blood Collection Tubes 365303 — BD Vacutainer® 9NC 109M Plus Blood Collection Tubes 360066 — BD Vacutainer® 9NC 0.109M Buffered Trisodium Citrate Plus Blood Collection Tubes 360067 — BD Vacutainer® 9NC 0.129M Plus Blood Collection Tubes 360086 — BD Vacutainer® 9NC 0.109M Buffered Trisodium Citrate Plus Blood Collection Tubes 363046 — BD Vacutainer® 9NC 0.109M Buffered Trisodium Citrate Plus Blood Collection Tubes

IVDD Conformity Assessment Route:	Annex III (excluding Annex III.6)
GMDN:	47592

**** Applies to Catalogue #363095 only***

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 AMD 2019** 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 11737-2:2020** 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 18113-3:2009** In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 3: In vitro diagnostic instruments for professional use (ISO 18113-3:2009) **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 AMD 2021** 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 17141:2020** Cleanrooms and associated controlled environments – Biocontamination control **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

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

DATE OF ISSUE: 07-Feb-2022

Signature: _____

Anne Zavertnik

Vice President, Regulatory Affairs

Integrated Diagnostic Solutions

Document Number: VR4310009

VERSION HISTORY Current Version Prepared By: Kelly Hilliger / Matthew Tennen	
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 Catalogue numbers 364306 and 364307 as per ACR PAS-000338. Update to harmonised and non-harmonised standards.
C	Removal of Catalogue numbers 364306 and 364307 as per cancellation of ACR PAS-000338. 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 Authorized Rep: BD Switzerland; updated EN ISO 13485-2012 to 2016; changed authorized signature to Kay Taylor.
F	Added new catalog numbers, 360066, 360067, 360086 for prebarcoded product requested by European marketing, ACR PAS-2019-0075 Serialization of Product on Unit Level with Barcode (Universal Specimen Identification – USI).
G	Per ACR PAS-2020-0072, added catalog number 363046. Updated standard EN ISO 11737-2:2009 to EN ISO 11737-2:2020. Removed reference to reagent standard EN ISO 18113-2 as this standard is not applicable to Citrate Plasma Tube device.
H	Updated standards per CP BDVS-2021-01-18-102351: • Replaced EN ISO 14698-1:2003 and EN ISO 14698-2:2003 with standard EN 17141:2020. Added reference to standard EN ISO 18113-3:2009. Changed authorized signature to Anne Zavertnik. Updated reference to EN ISO 11137-1:2015 to EN ISO 11137-1:2015 AMD 2019 and update ref to EN ISO 11737-1:2018 to EN ISO 11737-1:2018 AMD 2021 per BDVS-2021-12-17-102739 Revised GMDN Code 42585 to 47592.