

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 *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
IVDD Classification:	Non Annex II <i>In Vitro</i> Diagnostic Medical Device	
IVDD Conformity Assessment Route:	Annex III (excluding Annex III.6)	
GMDN:	42585	

* 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 13485:2012 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

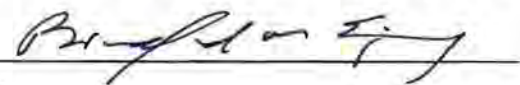
Medical devices - Application of usability engineering to medical devices **EN ISO 18113-1: 2011** In vitro diagnostic medical devices – Information supplied by the manufacturer (Labelling). Part 1: Terms, definitions and general requirements (ISO 18113-1:2009) **EN ISO 18113-2: 2011** In vitro diagnostic 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

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

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

Signature: 

Brad Spring

Vice President, Regulatory Affairs

BD Life Sciences

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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 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.