

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:	<table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left;">Catalogue number</th> <th style="text-align: left;">Device name</th> </tr> </thead> <tbody> <tr> <td>360210</td> <td>BD Vacutainer® PrecisionGlide™ Multiple Sample Needle</td> </tr> <tr> <td>360211</td> <td>BD Vacutainer® PrecisionGlide™ Multiple Sample Needle</td> </tr> <tr> <td>360212</td> <td>BD Vacutainer® PrecisionGlide™ Multiple Sample Needle</td> </tr> <tr> <td>360213</td> <td>BD Vacutainer® PrecisionGlide™ Multiple Sample Needle</td> </tr> <tr> <td>360214</td> <td>BD Vacutainer® PrecisionGlide™ Multiple Sample Needle</td> </tr> <tr> <td>360215</td> <td>BD Vacutainer® PrecisionGlide™ Multiple Sample Needle</td> </tr> </tbody> </table>	Catalogue number	Device name	360210	BD Vacutainer® PrecisionGlide™ Multiple Sample Needle	360211	BD Vacutainer® PrecisionGlide™ Multiple Sample Needle	360212	BD Vacutainer® PrecisionGlide™ Multiple Sample Needle	360213	BD Vacutainer® PrecisionGlide™ Multiple Sample Needle	360214	BD Vacutainer® PrecisionGlide™ Multiple Sample Needle	360215	BD Vacutainer® PrecisionGlide™ Multiple Sample Needle
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Classification:	Class IIa														
Conformity Assessment Route:	Conformity is established through application of the procedures described in Annex V and Annex VII of the European Medical Devices Directive 93/42/EEC.														
GMDN:	35209 – Blood collection needle basic														
Notified Body:	British Standards Institution (BSI), Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PP, UK. (NB Number 0086)														
CE Certificate Number:	00362														
Date of issue of original CE Certificate:	22 December 1994														

We herewith declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. All supporting documentation is retained under the premises of the manufacturer.

List of Harmonised Standards:

EN ISO 13485:2012 Medical devices – Quality management systems – Requirements for regulatory purposes
EN 556-1:2001 Sterilization of medical devices - Requirements for medical devices to be designated 'STERILE'
EN ISO 14971:2012 Medical devices – Application of risk management to medical devices
EN ISO 11137-1:2006 Sterilization of healthcare products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
EN ISO 11137-2:2012 Sterilization of healthcare 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 validation of a sterilization process
EN ISO 10993-1:2009 Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
EN ISO 10993-3:2014 Tests for genotoxicity, carcinogenicity and reproductive toxicity
EN ISO 10993-5:2009 Tests for in vitro


cytotoxicity **EN ISO 10993-6:2009** Tests for local effects after implantation **EN ISO 10993-11:2009** Tests for systemic toxicity **EN ISO 10993-12:2012** Sample preparation and reference materials **EN ISO 10993-13:2010** Biological evaluation of medical devices Part 13: Identification and quantification of degradation products from polymeric medical devices **EN ISO 10993-15:2009** Biological evaluation of medical devices Part 15: Identification and quantification of degradation products from metals and alloys **EN ISO 10993-17:2009** Biological evaluation of medical devices Part 17: Establishment of allowable limits for leachable substances **EN ISO 10993-18:2009** Biological evaluation of medical devices Part 18: Chemical characterization of materials **EN ISO 11607-1:2009** Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems **EN ISO 11607-2:2006** Packaging for terminally sterilized medical devices Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2006) **EN ISO 22442-3:2007** Medical devices utilizing animal tissues and their derivatives: Validation of the elimination and/or inactivation of viruses and transmissible spongiform encephalopathy (TSE) agents **EN 1041:2008** Information supplied by the manufacturer with medical devices **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:

EN ISO 6009:2016 Hypodermic needles for single use – Colour coding for identification **ISO 14001:2015** Environmental management systems - Requirements with guidance for use **EN ISO 9626:2016** Stainless steel needle tubing for the manufacture of medical devices **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 **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 **EN ISO 14698-1:2003** Cleanrooms and associated controlled environments. Biocontamination control. General principles and methods **EN ISO 14698-2:2003** Cleanrooms and associated controlled environments. Biocontamination control. Evaluation and interpretation of biocontamination data **EN 62366-1:2015** Medical devices Part 1: Application of usability engineering to medical devices - CORR: January 31, 2016 **EN ISO 10993-2:2006** Animal Welfare Requirements **EN ISO 10993-10:2013** Tests for irritation and skin sensitization **EN ISO 10993-4:2017** Selection of tests for interactions with blood **EN ISO 22442-1:2015** Medical devices utilizing animal tissues and their derivatives: Application of risk management **EN ISO 22442-2:2015** Medical devices utilizing animal tissues and their derivatives: Controls on sourcing, collection and handling **EN ISO 11137-3:2017** Sterilisation of health care products – Radiation – part 3: Guidance on dosimetric aspects of development, validation and routine control **EN ISO 11737-1:2018** Sterilization of medical devices – Microbial methods- Part 1 : Determination of a population of microorganisms on products

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

Document Number: VR4390001

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)
C	Update to harmonised and non-harmonised standards list
D	Update to harmonised and non-harmonised standards list
E	Update to harmonised and non-harmonised standards list. Removal of India specific catalogue numbers 365073 and 365075 that were never manufactured.
F	Update harmonised EN ISO 11737-1:2006 to non-harmonised EN ISO 11737-1:2018 as per CAPA 325553.