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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** 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
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

Registered Office: Becton Dickinson UK Ltd. 1030 Eskdale Road, Wokingham, Berkshire, RG41 5TS. UK.
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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

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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)
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.