EU Declaration of Conformity

in accordance with Regulation (EU) 2017/745 of the European Parliament and of the Council

Legal Manufacturer:	Becton, Dickinson and Company (BD) 1 Becton Drive Franklin Lakes, NJ 07417-1885 USA
Authorised Representative:	BD Switzerland Sàrl Terre Bonne Park -A4 Route de Crassier 17 1262 Eysins Switzerland
Manufacturing Sites:	Becton, Dickinson and Company (BD) 150 South First Avenue Broken Bow, NE 68822 USA Nypro Ltd. Corke Abbey Bray Co. Wicklow Ireland
Product Trade Name:	BD Vacutainer® One Use Holder
SKU:	364815
Basic UDI-DI:	038290ZKHHKZQEKP
GMDN Code and Term:	Code: 37566 Term: Blood collection tube holder, single-use
Risk Classification and Rule:	Class I, Annex VIII, Rule 1
Intended Purpose/Intended Use:	BD Vacutainer® One Use Holder is a single-use, non-sterile device used to attach and hold a BD Vacutainer® Brand venous access device such as a blood collection needle, blood collection set or luer adapter during venipuncture and to connect the device to a BD Vacutainer® blood collection tube.
Notified Body:	Not Applicable
Conformity Assessment Route:	The Conformity is established through the application of requirements described in Annex II Technical Documentation and Annex III Technical Documentation on post-market surveillance of Regulation (EU) 2017/745
Certificate Number:	Not Applicable

Date of issuance of original EC certificate:	Not Applicable

This document is issued under the sole responsibility of the Legal Manufacturer. We hereby declare the conformity of the above mentioned products with Regulation (EU) 2017/745 of the European Parliament and of the Council and, if applicable, with any other relevant Union legislation that provides for the issuing of an EU declaration of conformity. The device is developed and manufactured in compliance with the Regulation (EU) 2017/745 and applied standards described in Table 1 here within.

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Table 1. Standards for BD Vacutainer® One Use Holder

Standard Number: Version Year	Standard Title	Standard Applied (Full or Partial). Justification provided for partially applied Standards
Quality Standard		
EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes	Full
Risk Management Standard		
EN ISO 14971:2012	Medical devices - Application of risk management to medical devices	Full
Biocompatibility Standards		
EN ISO 10993-1:2009/AC:2010 ISO 10993-1:2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	Full
EN ISO 10993-2:2006 ISO 10993-2:2006	Biological evaluation of medical devices - Part 2: Animal welfare requirements	Full
EN ISO 10993-5:2009 ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	Full
EN ISO 10993-10:2013 ISO 10993-10:2010	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	Full
EN ISO 10993-12:2013 ISO 10993-12:2012	Biological evaluation of medical devices – Part 12: Sample preparation and reference materials	Full
Labelling Standards		
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	Full
EN 1041:2008 + A1:2013	Information supplied by the manufacturer of medical devices	Full
Cleanroom Standard		
ISO 14644-1:2015	Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration	Full
Usability Standard		
EN 62366-1:2015/ AC:2016-09	Medical devices - Part 1: Application of usability engineering to medical devices	Full
Guidance Document		
MEDDEV 2.7/1 Revision 4	Clinical evaluation: Guide for manufacturers and notified bodies	Full

No common specifications have been identified for BD Vacutainer® One Use Holder at this time.

Place of Issue: Becton, Dickinson and Company (BD), 1 Becton Drive, Franklin Lakes, NJ 07417-1885 USA.

Signature: Kay A Taylor Date of Issue: 29-May-2020

Kay Taylor, VP Regulatory Affairs, Life Sciences

REVISION HISTORY

Revision	Date	Detailed Change Description
1	31-Jan-2020	New document created to meet Regulation (EU) 2017/745 compliance.