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:	Becton Dickinson Ireland Ltd. Donore Road Drogheda, Co. Louth A92 YW26, Ireland
Manufacturing Sites:	**BD Vacutainer® Pronto™ Quick Release Needle Holder:** Nipro Medical Industries Ltd. Tatebayashi Plant 2-19-64, Matsubara Tatebayashi-shi, Gunma, 374-8518 Japan **BD Vacutainer® Standard Yellow Holder:** Becton, Dickinson and Company (BD) 1575 Airport Road PO Box 2128 Sumter, SC 29153 USA
Product Trade Name:	BD Vacutainer® Pronto™ Quick Release Needle Holder BD Vacutainer® Standard Yellow Holder
Risk Classification and Rule:	Class I, Annex VIII, Rule 1
Intended Purpose/Intended Use:	**BD Vacutainer® Pronto™ Quick Release Needle Holder**: BD Vacutainer® Pronto™ Quick Release Needle Holder is a non-sterile reusable device used to attach and hold a BD Vacutainer® venous access device (i.e., needle, blood collection set) during venipuncture and to connect these devices to BD Vacutainer® Tubes. **BD Vacutainer® Standard Size Yellow Holder:** BD Vacutainer® Standard Yellow Holder is intended to be coupled with a BD Vacutainer® blood collection needle or other venous access device (i.e. blood collection set) in order to facilitate the insertion of the needle into the patient's vein and to help guide the evacuated blood collection tube onto the non-patient (NP) end of the needle during the blood collection process.
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 devices are developed and manufactured in compliance with the Regulation (EU) 2017/745 and applied standards described in Table 2 here within.

EU Declaration of Conformity

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

Table 1. Basic UDI-DI and additional Product Identification Information

Basic UDI-DI	Product Trade Name	SKU	Risk Classification and Rule	GMDN Code – Term Name
038290YSFSSDTHR4	BD Vacutainer® Pronto™ Quick Release Needle Holder	368872	Class I, Rule 1	Code: 36188 Term: Blood collection tube holder, reusable
038290HHAJBGWQZJ	BD Vacutainer® Standard Yellow Holder	364879		

EU Declaration of Conformity

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

Table 2. Standards for BD Vacutainer® Pronto™ Quick Release Needle Holder and BD Vacutainer® Standard Yellow 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
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® Pronto™ Quick Release Needle Holder and BD Vacutainer® Standard Yellow Holder at this time.

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

Signature: _____ Date of Issue: 18-October-2021

Name/Title/Position: Anne Zavertnik/Vice President, Regulatory Affairs - IDS

REVISION HISTORY

Revision	Date	Detailed Change Description
1	31-Jan-2020	New document created to meet Regulation (EU) 2017/745 compliance.
2	13-Oct-2021	Per CC-2021-91: Revised Authorization Representative address to: Becton Dickinson Ireland Ltd., Donore Road, Drogheda, Co. Louth, A92 YW26, Ireland