Quality System Approval Certificate

Medical Devices Directive 93/42/EEC

*The National Standards Authority of Ireland as a duly designated Notified Body, (identification number **0050**), for the purposes of the European Communities (Medical Devices) Regulations (S.I. No. 252 of 1994)*

APPROVES THE QUALITY SYSTEM APPLIED BY

Becton, Dickinson and Company

1 Becton Drive
Franklin Lakes
NJ 07417-1880
USA

to the Product Family

Blood Collection/intravenous fluid Administration Sets (VACUTAINER® Brand)

GMDN Code: 58490

on the basis of examination under the requirements of Directive 93/42/EEC on Medical Devices, Annex II, excluding (4)

*The use of the NSAI Notified Body identification number **0050** in conjunction with CE Marking of Conformance for this product family is hereby authorised.*

Registration Number:	**252.191**
Original Approval:	**27 April 1997**
Last Amended on:	**10 July 2018**
Remains valid until:	**26 April 2023**

Signed:

Approved by:
Geraldine Larkin
Chief Executive Officer, NSAI

Approved by:
Susan Murphy
European Medical Device Operations Manager

This certificate remains valid on condition that the Approved Quality System is maintained in an adequate and efficacious manner.
Details of the operational locations included within the scope of this approval can be obtained from NSAI

In the case of a Class III device, this certificate must be supported by a valid design examination certificate

National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland.

1 Becton Drive
Franklin Lakes, New Jersey
tel: 201.847.6800
www.bd.com

BD
Helping all people
live healthy lives

DECLARATION OF CONFORMITY

Legal Manufacturer:	*Name and Address* Becton, Dickinson and Company (BD) 1 Becton Drive Franklin Lakes NJ 07417 USA	
Authorized Representative:	*Name and Address* Becton, Dickinson and Company Belliver Industrial Estate Belliver Way Roborough Plymouth, PL6 7BP, United Kingdom	
Products:	Product Family ▪ *BD Vacutainer® Push Button Blood Collection Set and BD Vacutainer® UltraTouch™ Push Button Blood Collection Set*	
Device Name:	Catalog Numbers **367338** BD Vacutainer® Push Button Blood Collection Set, 21G x 3/4" x 7" **367336** BD Vacutainer® Push Button Blood Collection Set, 23G x 3/4" x 7" **367335** BD Vacutainer® Push Button Blood Collection Set, 25G x 3/4" x 7" **367344** BD Vacutainer® Push Button Blood Collection Set, 21G x 3/4" x 12" **367342** BD Vacutainer® Push Button Blood Collection Set, 23G x 3/4" x 12" **367341** BD Vacutainer® Push Button Blood Collection Set, 25G x 3/4" x 12" **367326** BD Vacutainer® Push Button Blood Collection Set, 21G x 3/4" x 12" **367324** BD Vacutainer® Push Button Blood Collection Set, 23G x 3/4" x 12" **367323** BD Vacutainer® Push Button Blood Collection Set, 25G x 3/4" x 12" **367393** BD Vacutainer® UltraTouch™ Push Button Blood Collection Set 21g x 3/4 x 7" **367392** BD Vacutainer® UltraTouch™ Push Button Blood Collection Set 23g x 3/4 x 7" **367391** BD Vacutainer® UltraTouch™ Push Button Blood Collection Set 25g x 3/4 x 7" **367365** BD Vacutainer® UltraTouch™ Push Button Blood Collection Set 21g x 3/4 x 7" **367364** BD Vacutainer® UltraTouch™ Push Button Blood Collection Set 23g x 3/4 x 12" **367363** BD Vacutainer® UltraTouch™ Push Button Blood Collection Set 25g x 3/4 x 12"	GMDN Code: 58490 GMDN Term: Blood Collection/intravenous fluid Administration Set

Classification:	*Provide Class of Device according to MDD* EU The BD Vacutainer® Push Button Blood Collection Set and BD Vacutainer® UltraTouch™ Push Button Blood Collection Set are Class IIa medical devices as defined in the Medical Devices Directive (93/42/EEC), Annex IX, Section 2.3, Rule 7: All surgically invasive devices intended for short-term use, to which the exceptions do not apply. Canada BD Vacutainer® Push Button Blood Collection Set and BD Vacutainer® UltraTouch™ Push Button Blood Collection Set are Class II medical devices as defined in the Schedule 1 of SOR/98-282. All surgically invasive medical devices are classified as class II.
Conformity Assessment Route:	*According to MDD* EU Annex II, Medical Device Directive 93/42/EEC

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.

Notified Body:	*Name and Address* National Standards Authority of Ireland (NSAI) 1 Swift Square Northwood Santry, Dublin 9, Ireland Phone: 353 (01) 807-3800 Fax: 353 (01) 807-3838
EC Certificate number:	252.191
Start of CE marking:	Original Approval: 27 April 1997
Manufacturing Site:	*Name and Address* Becton, Dickinson and Company (BD) 1575 Airport Road Sumter, SC 29153 USA Becton Dickinson Infusion Therapy Systems Inc. 9450 South State Street Sandy, Utah 84070 USA

Refer VTF0030-03 PBBCS Declaration of Conformity

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Date: November 06, 2015

Eileen Hiller

Eileen Hiller
Senior Staff Specialist Regulatory Affairs
Becton, Dickinson and Company (BD)

Revision History		
Current Revision Prepared By: P. Amato **Training Requirements For This Revision:** Regulatory Affairs [ ] No Training Required [X] Read Only [ ] Classroom Training [ ] Manufacturing facilities are to incorporate applicable sections of this document into their quality system.		
REVISION RECORD		
Rev. No.	**Revision Description**	**ECO No.**
01	Release the Declaration of Conformity for BD Vacutainer® Push Button Blood Collection Sets.	ECO191873
02	Corrected address error, correction of zipcode.	NA
03	Revised to include the BD Vacutainer® UltraTouch™ Push Button Blood Collection Set line extension. Corrected name of European Representative. Corrected name of Notified Body from Association to Authority	NA