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

Luer Adapters, Transfer Devices and Access Devices

on the basis of examination under the requirements of Annex II, Section 3 of Directive 93/42/EEC.
*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:	**252.548**
Original Approval:	**19 May 1997**
Last Amended on:	**03 March 2015**
Remains valid until:	**18 May 2018**

Signed:

Approved by:
Kevin D. Mullaney
Chief Executive Officer - NSAI Inc.

Approved by:
Susan Murphy
Risk Management Officer

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

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

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* Regulatory Affairs Manager, PAS Europe Becton, Dickinson and Company Belliver Industrial Estate Plymouth, PL6 7BP, UK	
Products:	Product Family • *BD Vacutainer® Luer Adapter*	
Device Name:	Catalog Numbers **367300** BD Vacutainer® Multiple Sample Luer Adapter	GMDN Code: 35075 GMDN Term: Luer adaptor
Classification:	*Provide Class of Device according to MDD* European Union Class I Sterile per Annex IX, rule 1 of the Medical Device Directive 93/42/EEC. Canada Class I per Schedule 1, Part 1, Rule 7, subrule 1 of the Canadian Medical Device Regulations (CMDR) SOR/98-282 which states that all other non-invasive devices are classified as Class I in which none of the indents apply.	
Conformity Assessment Route:	*According to MDD* 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 Association of Ireland (NSAI) 1 Swift Square Northwood Santry, Dublin 9 Ireland Phone: 353 (01) 807-3800 Fax: 353 (01) 807-3838
EC Certificate number:	252.548
Start of CE marking:	Original Approval: 19 May 1997

Manufacturing Site:	*Name and Address:* Becton, Dickinson and Company (BD) 1575 Airport Rd. Sumter, SC 29153

Refer VTF0003-02 Luer Adapter Declaration of Conformity

Date: December 9, 2014

Eileen Hiller

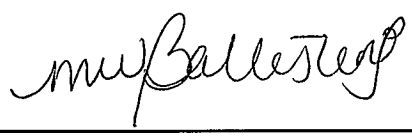
Eileen Hiller
Senior Staff Specialist Regulatory Affairs
Becton, Dickinson and Company

Revision History		
Current Revision Prepared By: Eileen Hiller **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® Luer Adapters.	ECO191905
02	Corrected the Authorized Representative with Becton, Dickinson and Company.	N/A

BD Diagnostics, Preanalytical Systems

Title: Declaration of Conformity for Medical Devices
Type: Department Form

BD *Declaration of Conformity*

Manufacturer:	Becton, Dickinson and Company BD Diagnostics, Preanalytical Systems 1 Becton Drive Franklin Lakes, NJ 07417-1880 Phone: 201 847 6800 Fax: 201 847 4858
Authorized Representative:	Becton, Dickinson and Company BD Diagnostics, Preanalytical Systems Belliver Industrial Estate Plymouth, PL6 7BP, England Phone: +44 1 865 748844 Fax: +44 1 752 779390
Conformity assessment procedure:	Annex I of Medical Device Directive 93/42/EEC as amended by 2007/47/EC Annex II of Medical Device Directive 93/42/EEC as amended by 2007/47/EC
Product:	BD Vacutainer® Luer-Lok™ Access Device described in VTF0039 (catalog # 364902)
	We hereby declare that the above-mentioned products manufactured after March 29, 2010 comply with the European Council Directive 93/42/EEC as amended by 2007/47/EC concerning medical devices and its relevant transposition into the national laws of the member states into which we place these devices.
Signed In Franklin Lakes on:	March 29, 2010
Name and Authority:	Wendy Ballesteros, Regulatory Affairs Manager Becton, Dickinson and Company BD Diagnostics, Preanalytical Systems
Signature:	

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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* Regulatory Affairs Manager, PAS Europe Becton, Dickinson and Company Belliver Industrial Estate Plymouth, PL6 7BP, UK	
Products:	Product Family • *BD Vacutainer® Blood Transfer Device*	
Device Name:	Catalog Numbers **364810** BD Vacutainer® Blood Transfer Device Holder with Pre-Attached Multiple Sample Female Luer Adapter	GMDN Code: 35384 GMDN Term: Syringe/Needle adaptor
Classification:	*Provide Class of Device according to MDD* European Union Class I Sterile per Annex IX, rule 1 of the Medical Device Directive 93/42/EEC Canada Class I per Schedule 1, Part 1, Rule 7, subrule 1 of the Canadian Medical Device Regulations (CMDR) SOR/98-282 which states that all other non-invasive devices are classified as Class I in which none of the indents apply.	
Conformity Assessment Route:	*According to MDD* Annex II, per 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 Association of Ireland (NSAI) 1 Swift Square Northwood Santry, Dublin 9, Ireland Phone: 353 (01) 807-3800 Fax: 353 (01) 807-3838
EC Certificate number:	252.548
Start of CE marking:	Original Approval: 19 May 1997
Manufacturing Site:	*Name and Address:* Becton Dickinson Caribe Ltd. Cerro Gordo Industrial Park Road 916, k.m. 0.8 No.98 San Lorenzo, Puerto Rico 00754

	BD Caribe Ltd. Road 31 km 24.3 Juncos, Puerto Rico 00777

Refer VYF0018-02 BTD Declaration of Conformity

Date: December 9, 2014

Eileen Hiller

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

Revision History		
Current Revision Prepared By: Eileen Hiller **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® Blood Transfer Device.	ECO191905
02	Corrected the Authorized Representative with Becton, Dickinson and Company.	N/A