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

Manual Blood Lancets, single-use
(BD Microtainer® Quikheel Lancets)

GMDN Code: 61578

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:	**252.189**
Original Approval:	**27 April 1997**
Last Amended on:	**08 January 2019**
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.

EC DECLARATION OF CONFORMITY

Legal Manufacturer:	Becton Dickinson and Company (BD) 1 Becton Drive Franklin Lakes, NJ 07417 USA
Authorised Representative:	Becton Dickinson and Company Belliver Industrial Estate Belliver Way Roborough Plymouth PL6 7BP UK
Manufacturing Site(s):	**Manufacturing**: BD Caribe, Ltd. Road 31, KM 24.3 Juncos, PR 00777-4010 **Manufacturing and Sterilization:** Becton Dickinson & Company (BD) 1575 Airport Road Sumter, SC 29153 **Sterilization**: STERIS Isomedix Services, Inc. State Road 690, KM 1.7 Vega Alta, PR 00692
Products:	**368102** BD Microtainer® Quikheel™ Lancet 0.85mm x 1.75mm **368103** BD Microtainer® Quikheel™ Lancet 1.00mm x 2.50mm

Classification:	EU Class IIa per Annex IX, Rule 6 of the Medical Device Directive (93/42/EEC) which states that all surgically invasive devices intended for transient use are Class IIA, in which none of the indents apply. Canada Class II per Schedule 1, Part 1, Rule 1, of the Canadian Medical Device Regulations (CMDR), SOR//98-282 which states that all surgically invasive devices are Class II in which none of the indents apply.
Conformity Assessment Route:	Annex II, Medical Device Directive 93/42/EEC as amended by Directive 2007/47/EC
GMDN:	GMDN Code: 61578 GMDN Term: Manual blood lancing device, single use.

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 at the premises of the manufacturer.

Standards:	EN 556-1:2001 EN 1041:2013 EN ISO 10993-1:2009 EN ISO 10993-11:2009 EN ISO 11137-1:2015 EN ISO 11137-2:2015 EN ISO 11137-3:2006 EN ISO 11607-1:2010 EN ISO 11607-2:2006 EN ISO 11737-1:2006 EN ISO 11737-2:2010 EN ISO 13485:2016 EN ISO 14971:2012 EN ISO 14155:2011 EN ISO 14644-1:2015

Notified Body:	National Standards Association of Ireland (NSAI) 1 Swift Square Northwood Santry, Dublin 9, Ireland Phone: 353 (01) 807-3800 Fax: 353 (01) 807-3838
CE Certificate Number:	252-189
Date of issuance of original CE certificate:	27 April 1997

Date: 12. December 2018

Bradford Spring
VP, Regulatory Affairs
BD Preanalytical Systems
Becton, Dickinson and Company (BD)

TITLE: Declaration of Conformity for BD Microtainer® Quikheel™ Lancet

REVISION HISTORY

Current Version Prepared By: Pamela Sanecki

REV.	Revision Description	Releasing ECO (if applicable)
01	Initial Release	ECO 191203
02	Corrected 368103 to remove "Preemie".	N/A
03	Corrected address error.	N/A
04	Correct typo "Quickheel" to "Quikheel"	N/A
05	Revision history inadvertently omitted from this version.	N/A
06	Removed EN-980 and replaced with EN ISO15223-1:2016 in the Standards section.	N/A
07	Updated GMDN code to 61578 as the old GMDN code was obsoleted. Updated revision dates in "Standards" as per V08-510-01.	N/A
08	Put document in correct template. Corrected rev date in Standard EN ISO 11137-3 from 2015 to 2006.	N/A
09	Updated authorized signature to Bradford Spring, VP Regulatory Affairs.	N/A 16-Nov-2018