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:	**27 March 2018**
Remains valid until:	**26 April 2021**

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 07417
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live healthy lives

EC DECLARATION OF CONFORMITY

Manufacturer:	Becton, Dickinson and Company 1 Becton Drive Franklin Lakes NJ 07417 USA
Authorized Representative:	Regulatory Affairs Manager, PAS Europe Becton, Dickinson and Company Belliver Industrial Estate Belliver Way Roborough Plymouth, PL6 7BP, United Kingdom
Manufacturing Site(s):	**Manufacturing and Packaging:** BD Caribe, Ltd 98 Cerro Gordo Industrial Park Road 916, k.m. 0.8 San Lorenzo, Puerto Rico 00754 BD Caribe Ltd. Road 31 Km.24.3 Juncos, PR 00777-4010 Puerto Rico
Products:	BD Microtainer® Quickheel™ Preemie Lancet existing in the following presentations: ▪ 0.85 mm x 1.75 mm: REF 368102 BD Microtainer® Quickheel™ Lancet existing in the following presentations: ▪ 1.00 mm x 2.5 mm: REF 368103
Classification:	*Provide Class of Device according to MDD* European Union Class IIA per rule 6 of Annex IX, Medical Devices 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) Canadian Medical Device Regulations SOR/98-282 which states that all surgically invasive devices are class II in which none of the indents apply.
Conformity Assessment Route:	*According to MDD* European Union Annex II, Medical Device Directive 93/42/EEC as amended by Directive 2007/47/EC
GMDN:	**GMDN Code:** 37466 **GMDN Term:** Manual blood lancet, single-use **Definition:** A small, sterile, sharply-pointed instrument (needle-like) designed to be used by healthcare provider to manually puncture the skin to obtain a small blood specimen or drain a cyst or boil. This is a single-use device.

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.

List of Harmonized Standards:	***EN 556*** *Sterilization of Medical Devices – Requirements for Medical Devices to be Designated Sterile* ***EN 980*** *Graphical Symbols for Use in the Labelling of Medical Devices* ***EN 1041*** *Information Supplied by the Manufacturer with Medical Devices* ***EN ISO 10993-1*** *ISO 10993-1: 2003 Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing* ***EN ISO 10993-5*** *ISO 10993-5: 1999 – Part 5: Tests for in vitro cytotoxicity* ***EN ISO 10993-11*** *ISO 10993-11: 2006- Part 11: Tests for systemic toxicity*
Notified Body:	National Standards Association of Ireland (NSAI) 1 Swift Square Northwood Santry, Dublin 9, Ireland Notified Body Number: 0050
EC Certificate Number	252.189
Date of issuance of the original CE certificate	Original Approval: 27 April 1997

January 6, 2015

Eileen Hiller

Eileen Hiller
Senior Staff Specialist, Regulatory Affairs
Becton, Dickinson and Company (BD)
Refer VTF0012-02 Quickheel Declaration of Conformity