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 Limited

Pottery Road
Dun Laoghaire
Co Dublin
Ireland

to the Product Family

Manual blood lancet, single-use (BD Microtainer® Contact-Activated Lancets)

GMDN Code: 37466

on the basis of examination under the requirements of Directive 93/42/EEC on Medical Devices Annex V.
*The use of the NSAI Notified Body identification number **0050** in conjunction with CE Marking of Conformance for this product family is hereby authorized.*

Registration Number:	**252.910**
Original Approval:	**18 April 2013**
Last Amended on:	**8 January 2019**
Remains valid until:	**17 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 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.

BD
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Helping all people
live healthy lives

DECLARATION OF CONFORMITY

Manufacturer:	Becton, Dickinson and Company Limited, Pottery Road, Dun Laoghaire, Co. Dublin, Ireland.
Authorised Representative:	NA
Products:	366592 BD Microtainer® Contact-Activated Lancet 1.5 mm x 30G (0.31 mm) 200 Pack 366593 BD Microtainer® Contact-Activated Lancet 1.8 mm x 21G (0.81mm) 200 Pack 366594 BD Microtainer® Contact-Activated Lancet 2.0 mm x1.5 mm 200 Pack 366599 BD Microtainer® Contact-Activated Lancet 2.0 mm x1.5 mm 100 Pack
Classification:	IIa
Conformity Assessment Route:	Annex V and VII
Declaration	We herewith declare that for the above mentioned products their product design meets the provisions of the Council Directive 93/42/EEC of 14 June 1993, as amended, concerning medical devices. All supporting documentation isretained at the premises of the manufacturer or subcontractor.
List of Harmonized standards:	EN 556-1, EN 980, EN 1041, EN ISO 10993-1/4/5/11, EN ISO 11137-1/2, EN ISO 11737-1, EN ISO 11607-1/2, EN ISO 13485, EN ISO 14971, EN ISO 14155
Tissue of Animal Origin Statement	All the materials used to manufacture the BD Microtainer® Contact Activated Lancets undergo safe conditions of processing: risk of animal derivatives was eliminated or minimized by each material supplier.
Notified Body:	NSAI 1 Swift Square Northwood Santry Dublin 9 Telephone: 353-1-807-3800 Number of Notified Body: 0050 Facility Certificate No.:M1362
EC Certificate number:	252.910
Start of CE marking:	April, 2013
Manufacturing site(s):	HTL Strefa S.A. ul.Adamowek 7, 95-035 Ozorkow, Poland

Date: 20 November 2014

Name Andrew Roche
Function QA/RA
Business Unit Medical Surgical Systems

Date: 20 November 2014

Cormac Reynolds
Director Becton, Dickinson and Company Limited
Diabetes Care