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
USA

to the Product Family

Hypodermic Syringes, insulin and general use (BD Micro-Fine™ +, BD Micro-Fine™ Plus, Micro-Fine™ IV, Ultra-Fine™ and Ultra-Fine™ II Insulin Syringes and Plastipak™ Allergy Syringes)

GMDN Code: 38501, 35904

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:	**252.140**
Original Approval:	**7 April 1995**
Last Amended on:	**27 August 2019**
Remains valid until:	**6 April 2020**

Signed:

Approved by:
Geraldine Larkin
Chief Executive Officer, NSAI

Approved by:
Elaine Darcy
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.