

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

Autoinjector Needles (BDTM, BD Micro-FineTM, BD Micro-FineTM+, BD Micro-FineTM Plus, BD Micro-Fine UltraTM, BD Micro-Fine UltraTM PRO, BD Ultra-FineTM, BD Ultra-FineTM PRO, BD VivaTM, BerliFine[®] Micro and Accu-Fine[®] Pen Needles)

GMDN Code: 44127

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 authorised.

Registration Number:

Original Approval:

Last Amended on:

Remains valid until:

Approved by

Chief Executive Officer, NSAI

Geraldine Larkin

Signed:

Approved by: Elaine Darcy European Medical Device Operations Manager

252.128

2 July 2019

22 February 1995

22 January 2020

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.

Cert-115: EC Annex V NL A4 (9)