



# 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 (BD™, BD Micro-Fine™, BD Micro-Fine™+, BD  
Micro-Fine™ Plus, BD Micro-Fine Ultra™, BD Micro-Fine Ultra™ PRO,  
BD Ultra-Fine™, BD Ultra-Fine™ PRO, BD Ultra-Fine™ 2nd Gen, BD  
Nano™, BD Viva™, 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.*

<b>Registration Number:</b>	<b>252.128</b>
<b>Original Approval:</b>	<b>22 February 1995</b>
<b>Last Amended on:</b>	<b>05 February 2021</b>
<b>Remains valid until:</b>	<b>26 May 2024</b>

**Signed:**

Approved by:  
Dr. Caroline Dore Geraghty  
Director, Medical Devices

Approved by:  
Dr. 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 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.**