



EU Quality Management System Certificate

Medical Device Regulation 2017/745

The National Standards Authority of Ireland as a duly designated Notified Body, (identification number 0050) for the purposes of the European Union under MDR 2017/745

APPROVES THE QUALITY MANAGEMENT SYSTEM APPLIED BY

Becton Dickinson and Company

**1 Becton Drive
Franklin Lakes,
NJ 07417
USA**

Manufacturer SRN: US-MF-000019182

Authorised Representative
Name and Address:

Becton Dickinson Ireland Ltd.
Donore Road
Drogheda
Co. Louth
A92 YW26
Ireland
SRN IE-AR-000007610

Device Group: Safety Pen Needles A01010102/44127
Risk Class: IIa

Conclusion: Quality Management System complies with the requirements of Annex IX, Chapter I & III of MDR 2017/745. The use of the NSAI Notified Body Identification Number 0050 in conjunction with CE Marking of Conformance for this product is hereby authorised.

Product Certificate Number:	745.021	Re-Issued Date:	-
First Issue Date:	23 December 2022	Expiry Date:	22 December 2027
Site Certificate Number:	MD 19.4912		

Signed:

Approved by:
Lisa Donlon
European Medical Device Operations Manager

Approved by:
Dr Majella Geraghty
European Medical Device Operations Manager

CONDITIONS AND LIMITATIONS: This certificate remains valid on condition that the Approved Quality Management System is maintained in an adequate and efficacious manner in line with the requirements of the Regulation. This certificate is based on examination of identified relevant CS, harmonised standards, test reports and audit reports maintained on file with NSAI. Information on examination and tests as per Annex XII, section 10, is available on request. Details of the current product range and operational locations included within the scope of this approval can be obtained from NSAI. Substantial Changes to the QMS or the product range covered must receive further approval from NSAI.

The validity of this certificate depends on conditions and/or is limited to the following:

National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland.

Appendix I

Certificate History

Product Certificate Number	Date of Issue	Type of Change <i>[supplemented, modified or re-issued]</i>	Details of Change
745,021	23 – 12 -2022	<i>New Application</i>	Initial Cert