



NSAI

EU Quality Management System Certificate Medical Device Regulation 2017/745

The National Standards Authority of Ireland (NSAI) 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**

Authorised Representative Name and Address: Becton Dickinson Ireland Ltd
Donore Road
Drogheda
Co Louth, A92 YW26
Ireland

Device Group: BD Fill and Filter Needles

Risk Class: I S

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:	745.004	Re-Issued Date:	-
First Issue Date:	29 April 2022	Expiry Date:	28 April 2027
Site Certificate Number:	MD 19.2305		

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. The audit performed by NSAI was limited to the aspects required under Article 52(7). Details of the current product range and operational locations included within the scope of this approval can be obtained from NSAI. This certificate is limited to the sterile, measuring or reusable aspect of the device. 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

Devices Covered by Certificate

300779	BD Nokor™ Admix Needle 18G 1.5"
300780	BD Nokor™ Admix Needle 16G 1"
305211	BD Blunt Fill Needle – Filter 18G 1.5"
305180	BD Blunt Fill Needle 18G 1.5"
305181	BD Blunt Fill Needle 18G 1"
305183	BD Blunt Fill Needle 20G 1"

Appendix II

Certificate History

Product Certificate Number	Date of Issue	Type of Change <i>[supplemented, modified or re- issued]</i>	Details of Change