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
Device Group:	Blood collection set, invasive (BD Vacutainer® Safety-Lok™ Blood Collection Set Product Family)
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:	745.056	Re-Issued Date:	
First Issue Date:	02 August 2023	Expiry Date:	01 August 2028
Site Certificate Number:	MD19.2137 / 1714		

Signed:

Approved by:
Dr Majella Geraghty
European Medical Device Operations Manager

Approved by:
Seán O'Callaghan
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:

Appendix I			
Certificate History			
Product Certificate Number	Date of Issue	Type of Change *[supplemented, modified or re-issued]*	Details of Change
n/a	n/a	*n/a*	n/a