

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 Limited

Donore Road Drogheda Co Louth **Ireland**

to the Product Family

Syringes (BD Plastipak TM and BD TM Perfusion)

GMDN Code: 47017

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 authorized.

> 252.156 **Registration Number:**

> **13 September 1995 Original Approval:**

> 12 September 2016 Last Amended on:

> 12 September 2019 Remains valid until:

Signed:

Kevin D. Mullaney

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.