EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 731353 R000

Manufacturer: Becton Dickinson Infusion Therapy Systems Inc.

Address:
9450 South State Street
Sandy
Utah
84070
USA

Single Registration Number: US-MF-000017719

EU Authorised Representative: Becton Dickinson Ireland Ltd.

Address:
Donore Road
Drogheda
Co. Louth
A92 YW26
Ireland

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: **2022-03-24**

Current Issue Date: **2024-09-20**

Starting Validity Date: **2024-09-20**

Expiry Date: **2027-03-23**

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Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Peripheral Intravascular Catheters and Cannulas	Class IIa

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2022-03-24	3249581	Issued
2022-12-08	3774021	Supplemented – Addition of Peripheral Intravascular Catheters and Cannulas
2023-12-20	30000284	Amended – Addition of subcontractor for manufacture of BD Venflon Pro, and for manufacture and ETO sterilization of BD Venflon and Venflon I devices. Addition of subcontractors for new modality of sterilization (E Beam) of BD Venflon Pro and Venflon Pro Safety devices.
Current	30249267	Restricted – Removal of device category 'Vascular Introducers'.

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