By Royal Charter

EU Quality Management System Certificate

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

MDR 766234 R000

Manufacturer: Arrow International LLC (Subsidiary of Teleflex Incorporated)

Address:
3015 Carrington Mill Blvd
Morrisville
North Carolina
27560
USA

Single Registration Number: US-PR-000023158

EU Authorised Representative: Teleflex Medical

Address:
IDA Business and Technology Park
Dublin Road
Athlone
Co. Westmeath
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 and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2023-02-13**

Current Issue Date: **2023-02-13**

Starting Validity Date: **2023-02-13**

Expiry Date: **2028-02-12**

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Device Schedule: Article 22.3 Systems and Procedure Packs

Device(s)	Highest Risk Classification within the System or Procedure Pack
Peripherally Inserted Central Catheter Procedure Packs	Class III, Implantable
Chronic Hemodialysis Catheter Procedure Packs	Class III, Implantable
Central Venous Catheter Procedure Packs	Class III
Acute Hemodialysis Catheter Procedure Packs	Class III
For Systems and Procedure Packs under Article 22.3, the Notified Body conformity assessment is limited to the aspects relating to ensuring sterility until the sterile packaging is opened or damaged.	

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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
Current	3808355	Issued

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

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A Member of the BSI Group of Companies.