

# EU Quality Management System Certificate

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

## MDR 745680 R000

**Manufacturer:** BD Switzerland Sàrl

**Address:**

Route de Crassier 17  
Business Park Terre-Bonne  
Bâtiment A4  
1262 Eysins  
Switzerland

**Single Registration Number:** CH-MF-000026539

**EU Authorised Representative:** Becton Dickinson Ireland Limited

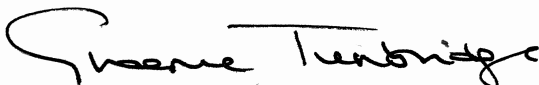
**Address:**

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 Medical Devices

First Issue Date: **2023-09-04**

Current Issue Date: **2024-02-07**

Starting Validity Date: **2024-02-07**

Expiry Date: **2028-09-03**

...making excellence a habit.™

# EU Quality Management System Certificate

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

## MDR 745680 R000

### Device Schedule: Class III and Class IIb devices

Class IIb under Rule 12	Intended purpose
Alaris GP Volumetric Pump	The Alaris™ Volumetric Pumps are intended for use by medical staff for the purpose of controlling infusion rate and volume.
Alaris VP Volumetric Pump	The Alaris™ Volumetric Pumps are intended for use by medical staff for the purpose of controlling infusion rate and volume.
Alaris Communication Engine	Alaris Communication Engine (ACE) is software application intended to transfer data sets to, and infusion data from, compatible BD infusion products via a network connection.
Alaris Editors	Alaris™ Editor is a PC-based application that allows hospitals to develop best practice data sets of IV medication dosing guidelines and configure general pump settings.
Class IIb	Intended purpose
Alaris Gateway Workstation	The Alaris™ Gateway Workstation is intended to be used within the hospital environment to provide mounting, power and communication support to the compatible Alaris™ infusion pumps. The Workstation transmit infusion data for the purpose of record keeping and pump alarm monitoring

First Issue Date: **2023-09-04**

Current Issue Date: **2024-02-07**

Starting Validity Date: **2024-02-07**

Expiry Date: **2028-09-03**

...making excellence a habit.™

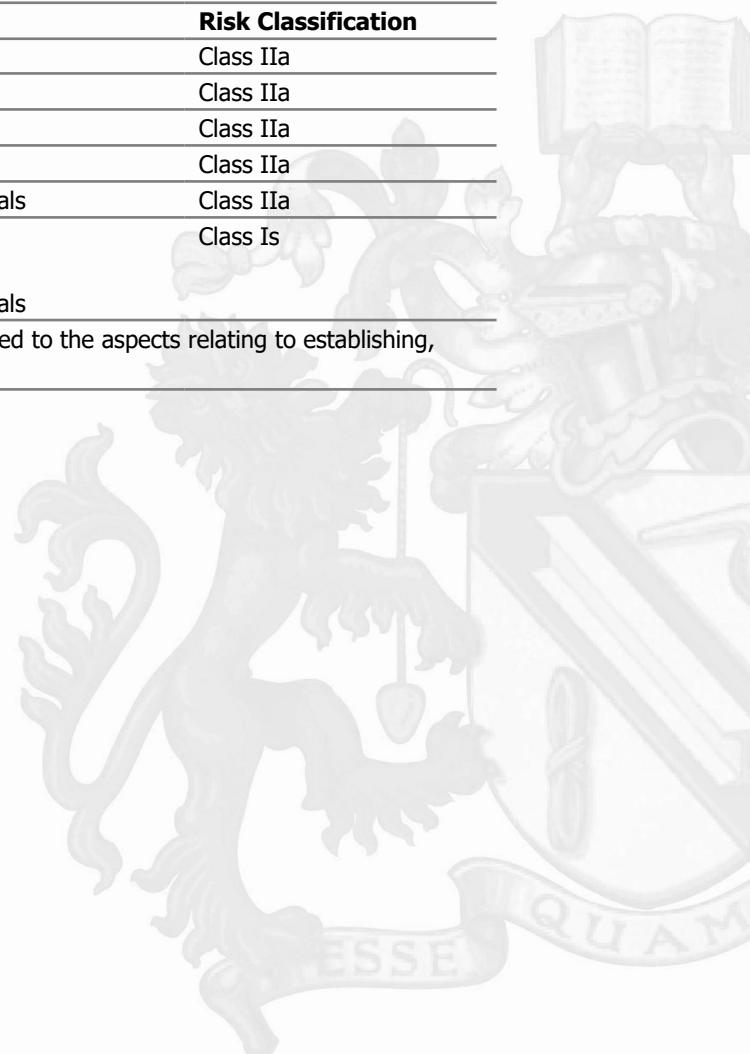
# EU Quality Management System Certificate

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

## MDR 745680 R000

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

Device(s)	Risk Classification
Sterile adapters and connectors	Class IIa
Sterile caps or obturators	Class IIa
Sterile extension lines	Class IIa
Sterile stopcocks	Class IIa
Sterile systems for reconstitution and administration of pharmaceuticals	Class IIa
Sterile adapters and connectors	Class Is
Sterile administration kits	
Sterile systems for reconstitution and administration of pharmaceuticals	
For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions.	



First Issue Date: **2023-09-04**

Current Issue Date: **2024-02-07**

Starting Validity Date: **2024-02-07**

Expiry Date: **2028-09-03**

...making excellence a habit.™

# EU Quality Management System Certificate

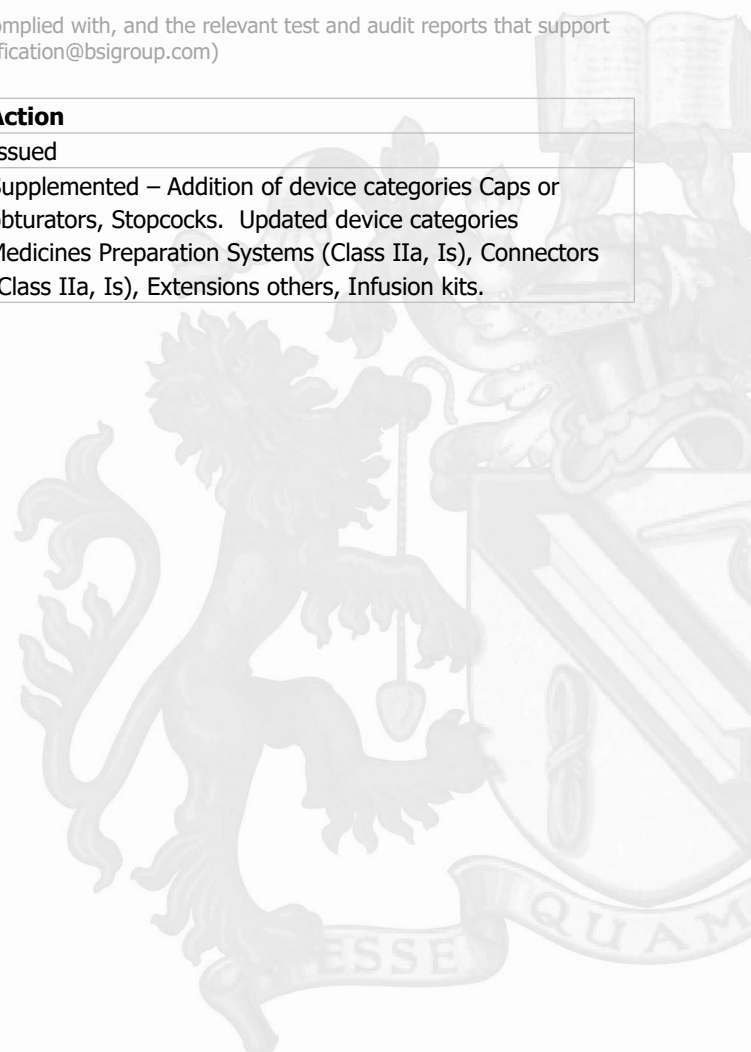
Regulation (EU) 2017/745, Annex IX Chapter I and III

**MDR 745680 R000**

## 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](mailto:Certificate.Verification@bsigroup.com))

Date	Reference Number	Action
2023-09-04	3789755	Issued
Current	30104934	Supplemented – Addition of device categories Caps or obturators, Stopcocks. Updated device categories Medicines Preparation Systems (Class IIa, Is), Connectors (Class IIa, Is), Extensions others, Infusion kits.



First Issue Date: **2023-09-04**

Current Issue Date: **2024-02-07**

Starting Validity Date: **2024-02-07**

Expiry Date: **2028-09-03**

...making excellence a habit.™

Page 4 of 4

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.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80  
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.  
A Member of the BSI Group of Companies.