By Royal Charter

EU Quality Management System Certificate

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

MDR 757642 R000

Manufacturer: C.R. Bard, Inc.

Address:
8195 Industrial Boulevard
Covington
Georgia
30014
USA

Single Registration Number: US-MF-000018892

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: **2022-11-21**

Current Issue Date: **2024-05-31**

Starting Validity Date: **2024-05-31**

Expiry Date: **2027-11-20**

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Device Schedule: Class III and Class IIb devices

Class III	Intended purpose
Temporary Pacing Electrode Catheter	See MDR 773854

Class IIb, Implantable	Intended purpose
Ureteral Stent	See MDR 773859 and MDR 773860

Class IIb	Intended purpose
Urethral Prostatic and Bladder Foley Catheters and Systems	Intended for the drainage and/or collection and/or measurement of urine
Lubricant Syringe	For urological use only. The Lube syringe is used to provide lubrication for easing the insertion of the catheter into the urethra.

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

Device(s)	Risk Classification
Urological Guidewire	Class IIa
Nephrostomy Balloon Dilation Catheters	Class IIa
Ureteral Access Catheters	Class IIa
Urine Collection Bags	Class Is
Urethral Intermittent Catheters	Class Is
Ureteral Balloon Dilation Catheter	Class Is
Catheter Valve	Class Is
Water Syringe	Class Is
Skin Prep Pad	Class Is
For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions.	

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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
2022-11-21	3537283	Issued
2024-01-17	30006620	Supplemented – Addition of the following device groups: Temporary Pacing Electrode Catheter Ureteral Stent Urological Guidewire (Updated from Urological Guidewire, Nitinol) Ureteral Balloon Dilation Catheter Catheter Valve Amended – Administrative change to Legal Manufacturer Address to read: C. R. Bard, Inc. 8195 Industrial Boulevard Covington, GA 30014 United States
Current	3718990	Supplemented - Addition of the following device groups: Urethral Prostatic and Bladder Foley Catheters and Systems Lubricant Syringe Nephrostomy Balloon Dilation Catheters Ureteral Access Catheters Water Syringe Skin Prep Pad

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