By Royal Charter

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No. **CE 515494**

Issued To: **C.R. Bard, Inc.**
8195 Industrial Blvd.
Covington
Georgia
30014
USA

In respect of:

See certificate scope page.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III certificate is required.

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

Gary E Slack, Senior Vice President - Medical Devices

First Issued: **2007-04-12** Date: **2020-09-25** Expiry Date: **2024-05-26**

...making excellence a habit.™

By Royal Charter

Certificate No: CE 515494

Certificate Scope:

Manufacture of sterile Foley catheters and accessories (including procedural kits and trays), urethral/intermittent catheters and accessories, ureteral catheter and accessories, gastrointestinal tubes, respiratory care products and wound suction/drainage products.

Those aspects of Annex V relating to securing and maintaining sterility in the manufacture of urethral/intermittent catheters and accessories, ureteral catheter and accessories, mucous specimen devices, ureteroscopic and kidney stone removal devices including cystoscopic irrigation bags and graspers and accessories (ureteral stent accessory), securement devices for catheters, bladder evacuation products, irrigation syringes, wound suction/drainage products, urinary drainage bags (including leg bags) and collection container/systems.

First Issued: **2007-04-12** Date: **2020-09-25** Expiry Date: **2024-05-26**

...making excellence a habit.™

EC Certificate - Production Quality Assurance

Supplementary Information to CE 515494

Issued To:

C.R. Bard, Inc.
8195 Industrial Blvd.
Covington
Georgia
30014
USA

Number	Device Name	Intended purpose per IFU
Class IIa		
MD 0102	Foley Catheters and Accessories (Including Procedural Kits and Trays)	---
MD 0102	Urethral/Intermittent Catheters and Accessories	---
MD 0102	Urethral Catheter and Accessories	---
MD 0102	Gastrointestinal Tubes	---
MD 0101	Respiratory Care Products	---
MD 0303	Wound Suction/Drainage Products	---

First Issued: **2007-04-12** Date: **2020-09-25** Expiry Date: **2024-05-26**

...making excellence a habit.™

EC Certificate - Production Quality Assurance

Supplementary Information to CE 515494

Issued To:

C.R. Bard, Inc.
8195 Industrial Blvd.
Covington
Georgia
30014
USA

Number	Device Name	Intended purpose per IFU
Class Is		
MD 0102	Urethal/Intermittent Catheters and Accessories	---
MD 0102	Ureteral Catheter and Accessories	---
MD 0106	Ureteral Catheter and Accessories	---
MD 0102	Mucous Specimen Devices	---
MD 0106	Ureteroscopic and Kidney Stone Removal Devices and Accessories (Including Cystoscopic Irrigation Bags and Graspers)	---
MD 0102	Securement Devices for Catheters	---
MD 0106	Bladder Evacuation Products	---
MD 0102	Irrigation Syringes	---
MD 0303	Wound Suction/Drainage Products	---
MD 0102	Urinary Drainage Bags (Including Leg Bags)	---
MD 0102	Collection Containers/Systems	---

First Issued: **2007-04-12** Date: **2020-09-25** Expiry Date: **2024-05-26**

...making excellence a habit.™

By Royal Charter

EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 515494**

Date: **2020-09-25**

Issued To: **C.R. Bard, Inc.**
8195 Industrial Blvd.
Covington
Georgia
30014
USA

Date	Reference Number	Action
12 April 2007	7814681	First Issue based on a subset of CE 00931.
3 October 2007		Addition of Integra Biotechnical LLC, Vista, California as a manufacturing subcontractor.
16 October 2009	7399834	Amendment to scope of certification for devices transferred from CE 515497. Addition of Bard Reynosa as a significant subcontractor.
26 February 2010	7482085	Extension to scope. Amendment to scope of certification for devices transferred from CE 515497. Addition of Bard Limited, Crawley as EU Rep.
29 March 2012	7816995	Certificate renewal.
19 November 2015	8414283	Extension of scope to include e-beam sterilisation, addition of significant subcontractor Rochester Medical Corporation at One Rochester Medical Drive and 455 Rochester Medical Drive; addition of Synergy Health AST, LLC, Denver Colorado.
12 August 2016	8586084	Addition of significant subcontractor Synergy Health AST LLC, Lima, Ohio.

By Royal Charter

EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 515494**

Date: **2020-09-25**

Issued To: **C.R. Bard, Inc.**
8195 Industrial Blvd.
Covington
Georgia
30014
USA

Date	Reference Number	Action
11 April 2017	8675581	Certificate renewal. Removal of subcontractor Integra Biotechnical LLC. Removal of sterilization activity by the subcontractor Davol Surgical Innovations S.A. de C.V. Addition of subcontractors Futurematrix Interventional, Athens, Texas; Omnitech Systems, Valparaiso, Indiana; Atrion Medical Products, Inc., Arab, Alaba; all for the activities manufacture and packaging.
21 December 2017	8849591	Addition of significant subcontractor for ETO sterilization, Sterigenics Belgium (Petit-Rechain) SA.
2 May 2018	8921549	Addition of significant subcontractor Iotron Industries USA for E Beam Sterilization. Addition of significant subcontractor Isomedix Operations, Inc. site in Ontario, California for E Beam Sterilization.
25 February 2019	7781192	Traceable to NB 0086.
18 December 2019	3081405	Update of EU Rep. to BD Switzerland Sarl.

EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 515494**

Date: **2020-09-25**

Issued To: **C.R. Bard, Inc.**
8195 Industrial Blvd.
Covington
Georgia
30014
USA

Date	Reference Number	Action
25 September 2020	3065608	Certificate Renewal Removal of scope – urinary drainage bags (including leg bags) and collection containers/systems (including volume measurement), urological guidewire and dilation products, irrigation syringes and accessories, ureteroscopic and kidney stone removal devices and accessories, Fecal and urinary incontinence; Ostomy products and accessories; metrology and volume measurements Modifying accessories listed as "including cystoscopic irrigation bags and graspers" to be included as device for ureteroscopic and kidney stone removal and specifying accessories as 'ureteral stent accessory' Merging of the Annex V scope related to sterility aspects into 1 paragraph Removal of subcontractors – Rochester Medical Corporation and Synergy Health AST Addition of subcontractors – Bard Regional Sterilization Facility, Smart World LLC, and Sterigenics US LLC in 3125 Wichita Court, Fort Worth, Texas Added "Control of Sterilization" service to Bard Sdn. Bhd., Kedah, Malaysia

EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 515494**
Date: **2020-09-25**
Issued To: **C.R. Bard, Inc.**
8195 Industrial Blvd.
Covington
Georgia
30014
USA

Date	Reference Number	Action
		Subcontractor address update for Bard Reynosa to "Blvd. Montebello No. 1, Parque Industrial Colonial, Reynosa, Tamaulipas, Mexico" Subcontractor name/address update for Bard Medical Division, Nogales, Mexico to "C. R. Bard Inc. PRODUCTOS PARA EL CUIDADO DE LA SALUD Carretera Internacional KM 6.5, Terrazas del Cid Nogales, Sonora, 84000, Mexico". Administrative update to add product supplementary table per MDP4500. Administrative update to spell out "Boulevard" in LM address Addition of gamma sterilization for Intermittent Catheters
Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3		
30 May 2023	3891029	Change in EU Authorized Representative from "BD Switzerland Sarl" to "Beckton Dickinson Limited Ireland"

Inspiring trust for a more resilient world.

30 May 2023

C.R. Bard, Inc.
8195 Industrial Blvd.
Covington
Georgia
30014
USA

To whom it may concern,

The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) and as per the guidance provided in MDCG 2020-3. The related MDD certificate specified below remains valid until the expiry date specified on the certificate.

Certificate	Directive and Annex	Reference Number	Changes approved
CE 515494	93/42/EEC Annex V	3891029	Change in EU Authorized Representative from "BD Switzerland Sarl" to "Beckton Dickinson Limited Ireland"

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,

Graeme Tunbridge
Senior Vice President, Medical Devices