By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 00931**

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 II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 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: **1995-10-10** Date: **2020-09-25** Expiry Date: **2024-05-26**

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Certificate No: CE 00931

Certificate Scope:

The design, development and manufacture of:

Non sterile Faecal Management Systems
Sterile Urological Guidewires
Sterile Intra Abdominal Pressure Monitoring Devices
Sterile Ureteral/Urethral, Suprapubic, Nephrostomy Catheters and Associated Procedure Packs
Sterile Medicated Urethral Catheters
Sterile Wound Suction/Drainage Kits
Sterile Ureteral Stents
Sterile Urine Collection System
Sterile Temporary Pacing Electrodes
Sterile Endourology Kits

First Issued: **1995-10-10** Date: **2020-09-25** Expiry Date: **2024-05-26**

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Supplementary Information to CE 00931

Issued To:

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Number	Device Name	Intended purpose per IFU
Class III		
---	Bardex IC Comprehensive Care Foley Tray (Procedure Packs)	See CE 543673
---	Bardex IC Foley Catheter	See CE 75331
---	Temporary Pacing Electrodes	See CE 607234
Class IIb		
MD 0102	Urological Catheters	Drainage and/or collection and/or measurement of urine
MD 0303	Wound Suction/Drainage Kits	Wound Drainage
MD 0204	Sterile Endourology Kits	Relieve obstruction in ureter
MD 0204	Ureteral Stents	Relieve obstruction in ureter
MD 0102	Urinary Collection System	Urine Collection
MD 0102	Urological Catheters, kits	Drainage and/or collection and/or measurement of urine

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Number	Device Name	Intended purpose per IFU
Class IIa		
MD 0102	Fecal Management Systems	---
MD 0102	Urinary Collection Container	---
MD 0102	Urological Catheters	---
MD 0106	Urological Guidewires	---
MD 0204	Urological Stents	---
MD 0102	Sterile Intra Abdominal Pressure Monitoring Devices	---
MD 0303	Wound Drainage	---

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Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

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Date:	**2020-09-25**
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Subcontractor:	**Service(s) supplied**
Angiomed GmbH & Co. Medizintechnik KG Wachhausstrasse 6 76227 Karlsruhe Germany	**Manufacture** **Packaging**
Atrion Medical Products Inc. 1426 Curt Francis Road Arab Alabama 35016 USA	**Manufacture** **Packaging**
Bard Medical Division 1211 Mary Magnan Boulevard Madison Georgia 30650 USA	**ETO Sterilization**

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Subcontractor:	**Service(s) supplied**
Bard Regional Sterilization Facilities 8195 Industrial Boulevard Covington Georgia 30014 USA	**ETO Sterilization**
Bard Sdn. Bhd. Lot 57C Kulim Industrial Estate 09000 Kulim Kedah Malaysia	**Control of Sterilization** **Manufacture** **Packaging**
BD Switzerland Sarl Terre Bonne Park - A4 Route de Crassier 17 1262 Eysins Switzerland	**EU Representative**

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Subcontractor:	**Service(s) supplied**
Biomerics FMI 1605 Enterprise Street Athens Texas 75751 USA	**Manufacture** **Packaging**
C.R. Bard, Inc. 428 Power House Road Moncks Corner South Carolina 29461 USA	**Manufacture** **Packaging**
C.R. Bard, Inc. Productos para El Cuidado de la Salud Carretera Internacional KM 6.5 Nogales Terrazas del Cid 84000 Sonora Mexico	**Assembly** **Manufacture** **Packaging**

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Subcontractor:	**Service(s) supplied**
C.R. Bard, Inc. 289 Bay Road Queensbury New York 12804 USA	**Assembly** **Manufacture** **Packaging**
Davol Surgical Innovations S.A. de C.V. Gral. Roberto Fierro No. 6408 Parque Industrial Aeropuerto Ciudad Juarez Chihuahua C.P. 32685 Mexico	**Crucial Supplier**
Memry Corporation 3 Berkshire Boulevard Bethel Connecticut 06801 USA	**Crucial Supplier**

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Subcontractor:	**Service(s) supplied**
Sterigenics Belgium (Petit- Rechain) SA Zoning Industriel de Petit-Rechain Avenue Andre Ernst 21 Verviers, Liege B-4800 Belgium	**ETO Sterilization**
Sterigenics US, LLC 84 Park Road Queensbury New York 12804 USA	**ETO Sterilization**
Synergy Sterilization (M) Sdn Bhd. Plot 203 Kuala Ketil Industrial Estate Kuala Ketil Kedah 09300 Malaysia	**ETO Sterilization** **Radiation (Gamma Sterilization)**

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EC Certificate - Full Quality Assurance System Certificate History

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Date	Reference Number	Action
10 October 1995		First issue.
15 May 1997		Marketing added as an activity. Monitor and accessories for urodynamic evaluation of voiding dysfunctions added to the scope. Bard at Clacton-on-Sea removed from listed sub-contractors. Bard Medical Division (BMD) and Bard Urological Division (BUD) added to list of sub-contractors
15 May 1997		Suction / irrigation and closed wound suction / drainage products added to the scope. Griffith Micro Science (Derby – UK) removed from sub-contractor listing
23 September 1997		Bard Medical Division (BMD) name changed to Bard Medical Division (Site1)

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Date	Reference Number	Action
21 June 2000		'Marketing' removed from list of activities. Biopty and monopty devices removed from the scope. Bard Medical Division (BMD) Nogales, Mexico; Bard Reynosa S.A. de C.V., Mexico and C.R Bard Inc, Glen Falls added to the list of sub-contractors. Bard Medical Division (Site 1) name changed back to Bard Medical Division (BMD).
21 December 2000		Changes to the address details. Procedural kits and trays relating to urine monitoring and collection systems removed from the scope. McGhan Medical Corporation (Freemont) added to list of subcontractors.
17 August 2005		The scope has been rationalised into sterile and non-sterile products. The activity of the sub-contractors has been updated. McGhan Medical Corporation name changed to Inamed Aesthtics. C.R. Bard In, Dymax Corp (Pittsburgh) added as a sub-contract manufacturer, assembly and packager. A History page has been added and certificate renewal

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Date	Reference Number	Action
07 February 2006		Subcontractors from Bard Limited, C.R Bard, Inc Georgia 30209 and Bard Sdn BhD, Kulim are being transferred to CR Bard Inc. Covington GA., following closure of manufacturing at Bard Ltd and Bard Ltd becoming authorised EU Rep
02 January 2007	4925702	CR Bard Sterilization facilities at Mary Magnan Blvd, Madison, GA 30650, added to list of subcontractors
12 April 2007	7022856	Amendment to scope of certification for products transferred to other Bard sites. Addition of Davel Surgical Innovation, Juarez, Mexico as a manufacturing sub-contractor
03 October 2007	7112332	Addition of Integra Biotechnical LLC, Vista, California as a manufacturing sub-contractor
16 October 2009	7399833 7444196	Amendment to scope of certification for devices transferred from CE 515495. Addition of Bard Shannon, Puerto Rico and Bard Reynosa as a significant subcontractors. Addition of Sterigenics Belgium and Bard Limited as significant subcontractors
26 February 2010	7482083	Amalgamation of scope and subcontractors from certificate CE 515495

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Date	Reference Number	Action
07 October 2010	7474855	Removal of significant subcontractor Integra Biotechnical LLC. Certificate renewal
14 May 2012	7805851	Extension to scope to include laser fibres for ablation and coagulation of tissue and removal of Contigen collagen implant/delivery system. Addition of significant subcontractor Laser Peripherals
20 November 2013	8073769	Extension to scope to include temporary pacing electrodes. Addition of significant subcontractor Sterigenics US, LLC, Queensbury
07 March 2014	8121540	Extension to scope to include endourology kits. Change of address for significant subcontractor Laser Peripherals from 1000 Boone Ave. N #300, Golden Valley, Minnesota 55427 to 13355 10th Avenue North, Plymouth, Minnesota 55441. Addition of significant subcontractor Angiomed GmbH & Co.

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Date	Reference Number	Action
30 September 2015	8418798	Removal of significant subcontractor Allergen Inc. Addition of significant subcontractor Barn Medical Division Regional Sterilization Facility (GA 30014), Futurematrix Interventional, Atrion Medical Products Inc, Omnitech Systems Inc and Memry Corporation. Addition of 'Control of Sterilisation' to services supplied by significant subcontractor Bard Sdn Bhd, Kedah, Malaysia. Services supplied by significant subcontractor Davol Surgical Innovations amended from Manufacture and Packaging to Crucial Supplier. Design responsibilities removed from multiple subcontractors as confirmed the legal manufacturer controls design. Minor amendments to names and addresses of all subcontractors (no change in legal entity or site location). Full revision of certificate scope to reflect the current Annex II Products. Certificate renewal

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Date	Reference Number	Action
06 February 2019	8856231	Removal of Sterile Porcine Collagen Mesh for Prolapse Repair and sterile electronic urine monitoring systems from the scope. Administrative update to add Sterile Endourology Kits. Administrative update to the scope to remove electrosurgical devices from sterile laser fibres and electrosurgical devices for tissue and calculi resection. Administrative update to the scope to specify sterile temporary pacing electrodes. Removal of significant subcontractor, Dymax Corporation. Addition of significant subcontractors Endosmart® Gesellschaft Fur Medizintechnik MbH, Heraeus Medical Components, LLC, Heraeus Medical Components, and Primo Medical Group, Inc. and Synergy Sterilization (M) Sdn Bhd.
25 February 2019	7781192	Traceable to NB 0086.
18 December 2019	3081410	Update of EU Rep. to BD Switzerland Sarl.

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Date	Reference Number	Action
Current	3065603	Certificate Renewal Removal of certificate scope - Sterile Laser Fibres for Tissue and Calculi Resection; Sterile Surgical Introducer and Suturing Guides; Sterile Non Absorbable Meshes for Prolapse (POP) Repair and Stress Urinary Incontinence (SUI) Kits; Sterile Brachytherapy Needles Removal of subcontractors - Bard Shannon Ltd Humacau PR, Bard Reynosa S.A. de C.V Mexico, EndoSmart, Heraeus Medical Components (St. Paul, MN and Plymouth, MN locations), Laser Peripherals, Primo Medical, Omnitech Systems Inc, Steri-Tech Inc Updated name from C.R. Bard, Inc. to Bard Medical Division; Bard Medical Division Regional Sterilization Facility Covington Operations to Bard Regional Sterilization Facilities; and from Futurematrix Interventional to Biomerics FMI Update services for Atrion Medical Products, Inc to specify Manufacture and Packaging; and removed crucial supplier Administrative update to Angiomed zip code and Sterigenics Belgium (Petit-Rechain) city name Administrative update to add product supplementary table per MDF4500. Administrative update to spell out "Boulevard" in LM address