

# 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**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

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**

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## Supplementary Information to CE 515494

Issued To:

**C.R. Bard, Inc.  
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Number	Device Name	Intended purpose per IFU
<b>Class IIa</b>		
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	---

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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

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Number	Device Name	Intended purpose per IFU
<b>Class Is</b>		
MD 0102	Urethral/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	---

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# EC Certificate - Production Quality Assurance

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

## List of Significant Subcontractors

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

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Date: **2020-09-25**  
Issued To: **C.R. Bard, Inc.**  
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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Atrion Medical Products Inc. 1426 Curt Francis Road Arab Alabama 35016 USA	<b>Manufacture Packaging</b>
Bard Medical Division 1211 Mary Magnan Boulevard Madison Georgia 30650 USA	<b>ETO Sterilization</b>
Bard Regional Sterilization Facilities 8195 Industrial Boulevard Covington Georgia 30014 USA	<b>ETO Sterilization</b>

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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Bard Reynosa S.A. de C.V. Blvd. Montebello No. 1 Parque Industrial Colonial Reynosa Tamaulipas Mexico	<b>Assembly Manufacture Packaging</b>
Bard Sdn. Bhd. Lot 57C Kulim Industrial Estate 09000 Kulim Kedah Malaysia	<b>Control of Sterilization Manufacture Packaging</b>
BD Switzerland Sarl Terre Bonne Park - A4 Route de Crassier 17 1262 Eysins Switzerland	<b>EU Representative</b>

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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Biomerics FMI 1605 Enterprise Street Athens Texas 75751 USA	<b>Manufacture Packaging</b>
C. R. Bard Inc. PRODUCTOS PARA EL CUIDADO DE LA SALUD Carretera Internacional KM 6.5 Terrazas del Cid Nogales Sonora 84000 Mexico	<b>Assembly Manufacture Packaging</b>
C.R. Bard, Inc. 428 Power House Road Moncks Corner South Carolina 29461 USA	<b>Manufacture Packaging</b>

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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
CR Bard Inc 289 Bay Rd. Queensbury New York 12804 USA	<b>Assembly Manufacture Packaging</b>
Davol Surgical Innovations S.A. de C.V. Gral. Roberto Fierro No. 6408 Parque Industrial Aeropuerto Ciudad Juarez Chihuahua C.P. 32685 Mexico	<b>Manufacture Packaging</b>
Iotron Industries USA 4394 East Park 30 Drive Columbia City Indiana 46725 USA	<b>Radiation (E Beam Sterilization)</b>

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**Subcontractor:**

**Service(s) supplied**

Isomedix Operations, Inc.  
1000 S. Sarah Place  
Ontario  
California  
91761  
USA

**Radiation (E Beam Sterilization)**

Omnitech Systems Inc.  
450 S Campbell St, Suite 2  
Valparaiso  
Indiana  
46385  
USA

**Manufacture  
Packaging**

Smart World LLC, dba Steri-Tek  
48225 Lakeview Blvd.,  
Fremont  
California  
94538  
USA

**Radiation (E Beam Sterilization)**

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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Sterigenics Belgium (Petit- Rechain) SA Zoning Industriel de Petit-Rechain Avenue Andre Ernst 21 Verviers, Liège B-4800 Belgium	<b>ETO Sterilization</b>
Sterigenics US, LLC 3125 Wichita Court Fort Worth Texas 76140 USA	<b>Radiation (Gamma Sterilization)</b>

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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.

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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.

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Date	Reference Number	Action
Current	3065608	<p>Certificate Renewal</p> <p>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</p> <p>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’</p> <p>Merging of the Annex V scope related to sterility aspects into 1 paragraph</p> <p>Removal of subcontractors – Rochester Medical Corporation and Synergy Health AST</p> <p>Addition of subcontractors – Bard Regional Sterilization Facility, Smart World LLC, and Sterigenics US LLC in 3125 Wichita Court, Fort Worth, Texas</p> <p>Added “Control of Sterilization” service to Bard Sdn. Bhd., Kedah, Malaysia</p>

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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