

EC Certificate - Full Quality Assurance System

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

No. CE 551333
Issued To: Bard Access Systems, Inc.
605 North 5600 West
Salt Lake City
Utah
84116
USA

In respect of:

The design and manufacture of sterile intravascular catheters, kits and associated accessories; implantable infusion ports and accessory devices; enteral feeding devices and accessories; safety infusion products; drainage catheters; peripheral nerve block and musculoskeletal needles.

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: **2009-08-16**

Date: **2021-04-19**

Expiry Date: **2024-05-26**

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Supplementary Information to CE 551333

Issued To:

**Bard Access Systems, Inc.
605 North 5600 West
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Number	Device Name	Intended purpose per IFU
Class III		
---	Central Circulatory System (CCS) Guidewires & Stylets	See CE 551348
---	Long Term Polyurethane Intravascular Catheters	See CE 551335
---	Long Term Polyurethane Hemodialysis Catheters	See CE 551337
---	Peripherally Inserted Central Catheter (PICC) Kits	See CE 551344
---	Long Term Silicone Intravascular Catheters and accessories	See CE 551334
---	Long Term Implanted Infusion Ports for Power Injection	See CE 551343
---	Long Term Implanted Infusion Ports	See CE 551341
---	Long Term Silicone Hemodialysis Catheters	See CE 551336

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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
Class IIb		
58891 11677 35419	Percutaneous Endoscopic Gastrostomy (PEG) Feeding Devices	Percutaneous Endoscopic Gastrostomy Device - For percutaneous placement of a long-term initial placement feeding and/or decompression device. Dual Port Feeding Adapter Device - For attachment to the proximal end of Bard silicone PEG tubes for administration of bolus and / or continuous feedings and delivery of medications.
47656	Jejunal Feeding/Gastric Decompression Tube Devices	For enteral nutritional support and decompression where feeding via the upper gastrointestinal tract is contraindicated. This includes, but is not limited to, post-upper gastrointestinal tract surgery, radiation therapy, chemotherapy, reflux and other conditions associated with nausea, vomiting and possible aspiration.

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Number	Device Name	Intended purpose per IFU
Class IIb		
38565 35419	Button Replacement Gastrostomy Devices	<p>The Button Replacement Gastrostomy Device is indicated for percutaneous placement of a low-profile, long-term gastrostomy feeding and decompression device through an established stoma. The stoma measuring device is used for the measurement of a well-established gastrostomy stoma tract for selection of an appropriate length Button device.</p> <p>The Continuous Feeding Tubes provide enteral feeding in patients requiring long-term nutritional support.</p> <p>The Bard Bolus Feeding Tubes deliver enteral feeding and/or medication into the Bard Button replacement gastrostomy device in patients requiring long-term nutritional support. Decompression Tubes provide gastric decompression in patients requiring long-term nutritional support or who are otherwise unable to expel gas or gastric contents.</p>
35419	Tri-Funnel Replacement Gastrostomy Tube Devices	Bard Tri-Funnel Gastrostomy Tubes are intended for percutaneous placement of a replacement gastrostomy feeding and/or decompression device into an established appropriately sized stoma.

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Number	Device Name	Intended purpose per IFU
Class IIb		
10696	Bard Navarre Percutaneous Biliary Drainage Catheter with Nitinol	The Bard Navarre Percutaneous Biliary Drainage Catheters are intended to be used for standard percutaneous transhepatic biliary drainage procedures that require internal retention (examples: obstructive jaundice, sepsis, hepatic decompensation, and preoperative decompression).
32151	Groshong Midline Catheters	The Groshong Midline catheter is used for peripheral placement for delivery of selected infusates (see Contraindications). For blood therapy, it is recommended that a 4 French or larger catheter be used.
32151	Per-Q-Cath Midline Catheters	The Per-Q-Cath Midline Catheters are indicated for short or long term peripheral access to the peripheral venous system for selected intravenous therapies and blood sampling. (See Contraindications) For blood therapy, it is recommended that a 4 French or larger catheter be used.

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Number	Device Name	Intended purpose per IFU
Class IIa		
MD 0106	Guidewires and Stylets	---
MD 0106	Guidewire Introducer Needles	---
MD 0106	Catheter Introducers	---
MD 0106	Port/Catheter Placement Accessories	---
MD 0106	Catheter Accessories	---
MD 0106	Surgical Accessories (hypodermic needles, safety scalpel, safety glide needle)	---
MD 0106	General Feeding Accessories (non-coring needles, vein pick, PEG introducer)	---
MD 0101 MD 0102	Pinpoint GT Needles	---
MD 0106	Site~Rite Ultrasound System Accessory (ultrasound probe covers, needle guides, ultrasound gel)	---
MD 0102	Safety Infusion Sets	---

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Number	Device Name	Intended purpose per IFU
Class IIa		
MD 0102	Short-Term Dialysis Catheters	---
MD 0102	Power-Trials Short Term Dialysis Catheters	---
MD 0106	Navarre Drainage Products: Bard Navarre Universal Drainage Catheters with Nitinol & Bard Navarre OPTI-DRAIN Multi-use Drainage Catheters	---
MD 0102	AccuCath Ace Intravascular Catheter	---
MD 0102	PowerGlide Midline Catheters	---
MD 0102	PowerGlide Pro Midline Catheters	---
MD 0102	Provena Midline Catheters	---
MD 0102	PowerMidline Catheters	---

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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: **2021-04-19**
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Subcontractor:	Service(s) supplied
Bard Medical Division 1211 Mary Magnan Boulevard Madison Georgia 30650 USA	ETO Sterilization
Bard Regional Sterilization Facilities 8195 Industrial Boulevard Covington Georgia 30014 USA	ETO Sterilization
Bard Reynosa S.A. de C.V. Blvd. Montebello No. 1 Parque Industrial Colonial Reynosa Tamaulipas Mexico	Labelling Manufacture Packaging

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Subcontractor:	Service(s) supplied
Bard Shannon Ltd. San Geronimo Industrial Park Lot # 1 Road #3, km 79.7 Humacao 00791 Puerto Rico	Manufacture Packaging
BD Switzerland Sarl Route de Crassier 17 Business Park Terre-Bonne Batiment A4 1262 Eysins Switzerland	EU Representative
C.R. Bard 289 Bay Road Queensbury New York 12804 USA	Manufacture

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Subcontractor:	Service(s) supplied
C.R. Bard, Inc. Productos para El Cuidado de la Salud Carretera Internacional KM 6.5 Terrazas del Cid, Nogales Sonara 84000 Mexico	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	Manufacture Packaging
Forefront Medical Investment (Pte) LTD 35 Joo Koon Circle Singapore 629110 Singapore	Manufacture Packaging

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Subcontractor:	Service(s) supplied
Forefront Medical Technology (Jiangsu) Co,Ltd. No. 8 Changyang Road Wujin Economy Development Zone Changzhou Jiangsu Province 213145 China	Manufacture Packaging
Heraeus Medical Components, SRL Parque Industrial Zona Franca La Lima Guadalupe Building 29 Cartago 30106 Costa Rica	Manufacture
Lake Region Medical Ltd Butlersland New Ross Co. Wexford Ireland	Manufacture

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Subcontractor:	Service(s) supplied
Medron, LLC 1518 South Gladiola Street Salt Lake City Utah 84104 USA	Manufacture
Medron, LLC 4752 West California Avenue Salt Lake City UT 84104 USA	Manufacture
Primo Medical Group, Inc. 75 Mill Street Stoughton Massachusetts 02072 USA	Manufacture

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Subcontractor:	Service(s) supplied
<hr/> Steri-Tech, Inc. Road 701 KM 0.7 Salinas Industrial Park Salinas 00751 Puerto Rico	ETO Sterilization
<hr/> Vesta, Inc 9900 South 57th Street Franklin Wisconsin 53132 USA	Manufacture

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Date	Reference Number	Action
16 August 2009	7387812	First issue - Transfer from another Notified Body
04 February 2010	7482186	Removal of repair kits for catheters from scope, removal of Sterigenics, 5725 West Harold Gatty Drive from the list of subcontractors, correction of typos on subcontractor listing and certificate renewal
19 March 2010	7506775	Extension to scope to add drainage catheters
26 August 2010	7536348	Transfer of Spire Biomedical RetrO Hemodialysis Catheter to Bard Access Systems. Addition of Argon Medical to the list of significant subcontractors for manufacturing. Addition of Lemco Enterprises to the list of significant subcontractors for ETO Sterilization. Addition of Forefront Medical Technology to the list of significant subcontractors for Manufacture and Packaging. Addition of Sterigenics US, LLC to the list of significant subcontractors for ETO Sterilization.
23 December 2010	7620266	Addition of VLV Associates to the list of significant subcontractors for Manufacture.
29 June 2011	7700085	Addition of "bovine-derived medicinal intravascular catheter cuff" to product scope.
28 October 2011	7760202	Addition of "kits and associated accessories" to the scope.

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10 April 2012	7814693	Addition of Davol Surgical Innovations to the list of significant subcontractors for Manufacturing and Packaging.
29 August 2013	8015549	Forefront Medical address updated from Singapore to Changzhou, Jiangsu Province, China. Synergy Health, Spectra Medical Devices and Precision Needle Manufacturing added as significant subcontractors.
11 July 2014	8124783	Addition of two addresses for Jiangyin PureMED Products Co., LTD. to list of significant subcontractors for manufacturing and packaging. Addition of GOALS Sterilization Co., Ltd. to list of significant subcontractors for EtO sterilization.
08 December 2014	8179705	Addition of Midwest Sterilization Corporation to list of significant subcontractors for EtO sterilization.

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Date	Reference Number	Action
26 January 2015	8239880	Certificate renewal. Below subcontractors' addresses were updated: C.R. Bard Inc. (Sonora Mexico); Synergy Health. Remove the following subcontractors: Argon Medical; Bard Healthcare - Reynosa (Texas); Biosearch Medical Products; C.R. Bard (Madison Georgia USA); Classic Industries; Del Mar Medical Devices S.A. de C.V.; Galt Medical; GOALS Sterilization; Integra Biotechnical; Integra LifeSciences; Jiangyin PureMED Products; Lake Region Manufacturing; Lemco Enterprises; Midwest; Neometrics; Precision Needle Manufacturing; Spectra Medical Devices; Sterigenics US; Steris Isomedix Services; Steri-Tech; VLV Associates. Addition of the following new subcontractors: Integra Biotechnical S.A. de C.V.; STD Med; Vesta.
15 September 2015	8359853	Update address for Synergy Health AST, LLC. Addition of Bard Medical Division, Midwest Sterilization Corporation and Steri-Tech, Inc. to the List of Significant Subcontractors for ETO sterilization. Addition of Lake Region Medical, Lake Region Medical Ltd, Neometrics Costa Rica SRL and Neometrics, Inc. to the List of Significant Subcontractors for manufacturing.

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Date	Reference Number	Action
15 December 2016	8647073	Addition of "peripheral nerve block and musculoskeletal needles" to the product scope.
07 November 2018	8923915	Updated subcontractor name for the NeoMetrics Plymouth, Minnesota location to Heraeus Medical Components, LLC, removed NeoMetrics Costa Rica SRL and added Heraeus Medical Components, SRL, Parque Industrial Zona Franca La Lima, Guadalupe Building 29, Cartago 30106 Costa Rica. Updated subcontractor name for STD Med Inc. in Stoughton, MA to Primo Medical Group, Inc.
22 February 2019	7780646	Traceable to NB 0086.

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31 January 2020	9750253	<p>Certificate renewal. Reduction of scope to remove 'and bovine-derived medicinal intravascular catheter cuff'.</p> <p>Removal of subcontractors 'Bard Limited (Crawley)', 'Lake Region Medical (Minnesota)', and 'Midwest Sterilization Corporation (Texas)'. Addition of subcontractors 'BD Switzerland Sàrl, Route de Crassier 17, Business Park Terre-Bonne, Batiment A4, 1262 Eysins, Switzerland', 'Medron, LLC, 4752 West California Avenue, Salt Lake City, UT 84104, USA' and 'Forefront Medical Investment (Pte) LTD, 35 Joo Koon Circle, Singapore, 629110, Singapore'.</p> <p>Clarification of subcontractors' name and/or address in line with vendors' certificates ('Bard Shannon Ltd.', 'C R Bard' (Queensbury), 'C.R. Bard, Inc' (Nogales), 'CR. Bard, Inc' (Covington), 'Davol Surgical Innovations S.A. de C.V.', 'Medron, LLC', 'Steri-Tech, Inc'). Update of address for Integra Biotechnical S.A. de C.V. to 'Ferrocarril 17030 Interior 8, 16 & 17, Colonia Ninos Heroes Este, CP. 22120 Tijuana' in line with vendor certificate. Addition of supplementary information table.</p>
31 August 2020	3282172	Update to products table in supplementary information section to remove RetrO Long Term Silicone Hemodialysis Catheters.

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Current	3376118	Removal of subcontractor Synergy Health AST, LLC (San Diego, California, USA), Heraeus Medical Components, LLC (Plymouth, Minnesota, USA) and Integra Biotechnical S.A. de C.V. (Tijuana, Mexico).

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