

# EC Certificate - Full Quality Assurance System

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

**No.****CE 01467****Issued To:**

**Bard Peripheral Vascular Inc  
Trading as C.R. Bard Inc  
1625 West 3rd Street  
Tempe  
Arizona  
85281  
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: **1996-12-05**

Date: **2020-08-03**

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

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Page 1 of 5

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.

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Certificate No: CE 01467

## Certificate Scope:

**The design, development and manufacture of ePTFE Vascular Grafts with and without carbon, Balloon Expandable Stents, Percutaneous Transluminal Angioplasty Catheters, Percutaneous Catheters, Biopsy Needles and Instruments, Biopsy Accessories, Breast Localization Wires, Cardiovascular Patches, Fabrics, Felts, Pledgets, Carotid Shunts, Vascular Probes, Tapes, Vena Cava Filters, Filter Retrieval Devices, Implantable Markers, High Frequency Catheters, and Valvuloplasty Catheters.**

**Those aspects of Annex II related to securing and maintaining sterility in the respect of breast biopsy needle guides, breast biopsy distance rings, as well as inflation devices. Those aspects of Annex II related to maintaining the measuring function of inflation devices.**

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## Supplementary Information to CE 01467

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Number	Device Name	Intended purpose per IFU
<b>Class III</b>		
---	Breast Tissue Markers	See CE 594902
---	True™ Dilatation Balloon Valvuloplasty Catheter True™ Flow Valvuloplasty Perfusion Catheter	See CE 614922
---	Bard Carotid Bypass Shunts	See CE 90271
---	Expanded Polytetrafluoroethylene Cardiovascular Patches	See CE 85054
---	BARD Textile Surgical Fabrics, Felts, Pledgets, and Tapes	See CE 87585
---	Bard Parsonnet Vascular Probes	See CE 86405
---	Simon Nitinol Filter With The SNF/SL Delivery System and Denali Filter System	See CE 66233
---	RC15 Recovery Cone Removal System	See CE 66234

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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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Class IIb		
40808	Implantable Markers	Intended to attach to soft breast tissue at the surgical site during an open surgical breast biopsy or a percutaneous breast biopsy to radiographically mark the location of the biopsy procedure.
36035	Balloon Expandable Stents	Intended for primary stenting in patients with atherosclerotic disease of the peripheral arteries
35281	ePTFE Vascular Grafts with and without Carbon	Indicated for use as vascular prostheses. Certain configurations are intended for use as subcutaneous arteriovenous conduits for blood access, bypass, or reconstruction of peripheral arterial blood vessels. Other configurations are intended for bypass or reconstruction of peripheral arterial blood vessels.

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<b>Class IIa</b>		
MD 1104	Biopsy Needles and Instruments (Active)	---
MD 0106	Biopsy Needles and Instruments (Non-Active)	---
MD 0106	Biopsy Accessories	---
MD 0106	Breast Localization Wires	---
MD 0106	Percutaneous Transluminal Angioplasty Catheters	---
MD 0106	Percutaneous Catheters	---
MD 0106	High Frequency Catheters	---
<b>Class Is</b>		
MD 0106	Breast Biopsy Needle Guides	---
MD 0106	Breast Biopsy Distance Rings	---
<b>Class Im/Is</b>		
MD 0104	Inflation Devices	---

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# EC Certificate - Full Quality Assurance System

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

## List of Significant Subcontractors

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Subcontractor:	Service(s) supplied
Armor Plast Ltd. 235 B/U1, Bommasandra Industrial Area Hosur Road Bangalore 560 099 Karnataka India	Manufacture
Bard Reynosa S.A. de C.V. Blvd. Montebello No. 1 Parque Industrial Colonial Reynosa Tamaulipas Mexico	Manufacture
Bard Shannon Ltd. San Geronimo Industrial Park Lot #1 Road #3, Km 79.7 Humacao 00791 Puerto Rico	Assembly Manufacture Packaging

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Subcontractor:	Service(s) supplied
BD Caribe Ltd. Road 31 Km.24.3 Juncos, PR 00777-4010 Puerto Rico	Manufacture
BD Switzerland Sàrl Terre Bonne Park – A4 Route de Crassier 17 1262 Eysins Switzerland	EU Representative
Biomerics FMI 1605 Enterprise Street Athens Texas 75751 USA	Manufacture

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Subcontractor:	Service(s) supplied
BIP Biomedizinische Instrumente und Produkte GmbH AM Brand 1 82299 Türkenfeld Germany	Manufacture
C.R. Bard, Inc. 1211 Mary Magnan Boulevard Madison Georgia 30650 USA	ETO Sterilization
C.R. Bard, Inc. 289 Bay Road Queensbury New York 12804 USA	Manufacture

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Subcontractor:	Service(s) supplied
C.R. Bard, Inc. 8195 Industrial Boulevard Covington GA 30014 USA	ETO Sterilization Final Inspection
CareFusion 75 North Fairway Drive Vernon Hills Illinois 60061 USA	Manufacture
CareFusion 400 East Foster Road Mannford OK 74044 USA	Manufacture

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Subcontractor:	Service(s) supplied
CareFusion D.R. 203 Ltd Zona Franca las Americas, Km. 22 - E-1 Santo Domingo Dominican Republic	Manufacture
Clearstream Technologies Ltd Moyne Upper Enniscorthy Co. Wexford Ireland	Manufacture
Custom Tube Manufacturing LLC - Korea (CTMK) 38-4, Hyeonseok-ro 733beon-gil, Gwangjeok-myeo Yangju-si, Gykeonggi-do 111413 South Korea	Manufacture

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Subcontractor:	Service(s) supplied
Ferrosan Medical Devices Sp. z.o.o. ul. Koksowa 3 70-031 Szczecin Poland	Manufacture
Forefront (Xiamen) Medical Devices Co., Ltd. No. 28 Haijing East Road & No. 61 Haijing South Road Xiamen Area of China (Fujian) Pilot Free Trade Zone 361026 Xiamen, Fujian Republic of China	Manufacture
Forefront Medical Technology (Jiangsu) Co., Ltd. No. 8, Changyang Road Wujin Economy Development Zone 213145 Changzhou, Jiangsu Province China	Manufacture

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Subcontractor:	Service(s) supplied
Infus Medical (Thailand) Co., Ltd. 706 Moo 4, Bangpoo Industrial Estate I-EA-T Free Zone, Tambon Preaksa Amphoe Muang Samutprakarn Samutprakarn Province 10280 Thailand	Manufacture
MeKo Im Kirchenfelde 12-14 D-311157 Sarstedt/Hannover Germany	Manufacture
Servicios De Ensamble Internacionales S.A. DE C.V. (SEISA) Parque Industrial Aeropuerto Roberto Fierro y Francisco Sarabia CP 32685 Cd. Juarez, Chihuahua Mexico	Manufacture

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Subcontractor:	Service(s) supplied
Spectra Medical Devices, Inc. 260-F&H Fordham Road Wilmington Massachusetts 01887 USA	Manufacture
Sterigenics (Thailand) Ltd. 109/16 Eastern Seaboard Industrial Estate (Rayong), Moo 4 T. Pluakdaeng A. Pluakdaeng, Rayong Province 21140 Thailand	Radiation (Gamma Sterilization)
Sterigenics Belgium (Petit- Rechain) SA Zoning Industriel de Petit-Rechain Avenue Andre Ernst 21 Verviers, Liege B-4800 Belgium	ETO Sterilization

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**USA**

Subcontractor:	Service(s) supplied
Sterigenics Germany GmbH Kasteler Straße 45 65203 Wiesbaden Germany	ETO Sterilization
Sterigenics US, LLC 344 Bonnie Circle Corona California 92880 USA	Radiation (Gamma Sterilization)
Sterigenics US, LLC 84 Park Road Queensbury New York 12804 USA	ETO Sterilization

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**85281**  
**USA**

Subcontractor:	Service(s) supplied
Sterigenics US, LLC 10811 Withers Cove Park Drive Charlotte North Carolina 28278 USA	<b>Radiation (Gamma Sterilization)</b>
Sterigenics US, LLC 10821 Withers Cove Park Drive Charlotte North Carolina 28278 USA	<b>ETO Sterilization</b>
Steritec, Inc. PO Box 1969 1705 Enterprise Street Athens Texas 75751 USA	<b>ETO Sterilization</b>

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**USA**

Subcontractor:	Service(s) supplied
Steri-Tech, Inc. Road 701 KM 0.7 Salinas Industrial Park 00751 Salinas Puerto Rico	ETO Sterilization
Synergy Health AST, LLC 7225 North Noah Drive Saxonburg Pennsylvania 16056 USA	Radiation (E Beam Sterilization)
Synergy Health Ireland Ltd IDA Business & Technology Park Tullamore Co. Offaly Ireland	ETO Sterilization Radiation (E Beam Sterilization)

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### Subcontractor:

### Service(s) supplied

Synergy Health Westport Ltd  
 Lodge Road  
 Westport  
 County Mayo  
 Ireland

**Radiation (Gamma Sterilization)**

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Date	Reference Number	Action
05 December 1996		First Issued as Bard Radiology Division
27 November 1998		Addition of Subcontractors
22 September 1999		Addition of Subcontractors, and name change to Bard Peripheral Technologies Division
03 April 2001		Removal of Subcontractors, addition of Navarre Biomedical as a subcontractor and extension to scope to include Drainage Catheters and Percutaneous Access Sets
28 March 2002		Addition of NMT Medical Inc and Vena Cava/Recovery Filters and Delivery System products.
20 February 2004		Re-issue to new company name (Bard Peripheral Vascular Inc, Trading as C.R Bard Inc.) and location, new format certificate, 5 year renewal, addition of subcontractors.
03 March 2004		Certificate Correction, to remove class III statement
20 August 2004		Extension of scope to include Vascular Probes
27 January 2005		Extension to scope to include Vascular Prostheses, Textile Surgical Fabrics, Felts, Pledgets, Tapes, Pouches and Carotid Bypass Shunts (transferred from another Notified Body) and corrections to history page
28 April 2005		Extension to scope to include 'electrical biopsy devices'
07 December 2005		Extension to scope to include 'Non-sterile biopsy instruments'

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Date	Reference Number	Action
04 May 2006		Bard Shannon Limited, Humacao, Puerto Rico and Steritec Inc added to the list of subcontractors
22 December 2006		Remove Devon Medical from subcontractor list and change name of Futuremed to Futurematrix on subcontractor list. Certificate renewal
30 November 2007		Transfer manufacture of the Pusher wire to Glens Falls Operation.
17 October 2008	7278554	Extension to scope to include 'Breast Tissue Markers'. Addition of 'Regional Sterilization Facility' Madison, Georgia as an ETO Sterilization subcontractor.
15 September 2009	7432858	Addition of Sonion Polska Sp. to the List of Significant Subcontractors for the activity of Manufacture. Removal of Isotron Deutschland GmbH from the List of Significant Subcontractors as they are no longer used by the manufacturer. Removal of Bard Shannon Limited, Las Piedras, PR from the List of Significant Subcontractors as this site is no longer used by the manufacturer.
09 April 2010	7506166	Ymed added to the list of significant subcontractors. Bard Limited added to the list of significant subcontractors as EU Representative.
29 April 2010	7478580	Scope extension to include "Balloon Expandable Stents" to reflect their transfer from another notified body. Scope extension to include Biopsy Devices. Removal of Drainage Catheter, Percutaneous Access Sets from scope.

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Date	Reference Number	Action
26 January 2011	7624320	Extension to scope to include "Percutaneous Catheters".
29 July 2011	7663970	Add Spectra Medical Devices, Armor Plast, and Clearstream Technologies to the certificate as significant subcontractors for manufacturing. Add the activity of Final Inspection to the activities of the Bard Covington facility. Remove Atrion Medical and YMed from the list of significant subcontractors.
12 October 2011	7729821	Updated Sonion's address to reflect current facility.
24 November 2011	7650621	Certificate renewal
29 October 2012	7906898	Addition of SenoRx, Ferrosan Medical Devices, STERIS Isomedix Services, and Sterigenics US, LLC as significant subcontractors. Update of address for other subcontractors.
07 December 2012	7908880	Inclusion of FlowCardia's products into the scope. Addition of Teleflex Medical, Nutek Corporation, and Cybersonics, Inc. to the scope as significant subcontractors.
07 December 2012	7908881	Addition of FlowCardia and Servicios De Ensamble Internacionales S.A. DE C.V. (SEISA) as significant subcontractors.
25 January 2013	7933131	Addition of Infus Medical (Thailand) Co., Ltd. and Sterigenics US, LLC in Corona, CA as significant subcontractors.
17 July 2013	7969864	Addition of valvuloplasty catheters to scope.

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Date	Reference Number	Action
14 August 2014	8166170	Clarify scope item descriptions to be more consistent with ISO 13485 certificate. Correct typographical error in manufacturer address. Remove FlowCardia, Inc. as significant subcontractor. Add MeKo, Dymax Corporation, Precision Needle Manufacturing, Inc., and Loma Vista Medical, Inc. as significant subcontractors. Correct activity of Nutek Corporation from "Manufacture" to "E beam sterilization."
27 January 2015	8271704	Extension to scope to include inflation devices in regards to those aspects of Annex II related to securing and maintaining sterility as well as maintaining the measuring function. Addition of Forefront Medical Technology (Jiangsu) Co., Ltd. as a significant subcontractor for manufacturing.
25 June 2016	8516614	Remove Loma Vista Medical, Inc. as a significant subcontractor. Add Synergy Health AST, LLC as a significant subcontractor for sterilization. Update name and address information for Precision Needle Manufacturing, Inc. to Custom Tube Manufacturing LLC - Korea (CTMK).
29 November 2016	8636071	Certificate renewal. Remove Nutek Corporation as a significant subcontractor.
04 October 2017	8769413	Addition of site for subcontractor, Dymax.
19 February 2019	7780591	Traceable to NB 0086.

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Date	Reference Number	Action
23 January 2020	3108568	Addition of EU representative BD Switzerland Sàrl (Eysins, Switzerland). Addition of subcontractor CareFusion D.R. 203 Ltd (Santo Domingo, Dominican Republic), CareFusion (Vernon Hills, IL, USA), CareFusion (Mannford, OK, USA), BD Caribe Ltd (Juncos, Puerto Rico), Sterigenics USA, LLC (10811 and 10821, Charlotte, NC), and Forefront (Xiamen) Medical Devices Co., Ltd (Xiamen, Fujian, China). Removal of subcontractor Steris Isomedix Services (Spartanburg, SC, USA), Teleflex Medical (Plymouth, MN), SenoRx (Tempe, AZ, USA) and Sterigenics (Tustin, CA, USA). Removal of EU representative Bard Limited (West Sussex, UK). Change of subcontractor name from "Futurematrix Interventional" to "Biomerics FMI". Change of address of subcontractor Armor Plast Ltd from "235 (B)" to "235 B/U1". Addition of products table in supplementary information section.

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 Date: **2020-08-03**  
 Issued To: **Bard Peripheral Vascular Inc**  
**Trading as C.R. Bard Inc**  
**1625 West 3rd Street**  
**Tempe**  
**Arizona**  
**85281**  
**USA**

Date	Reference Number	Action
Current	3089893	Certificate Renewal; Removal of subcontractors: Angiomed (Germany), Cybersonics (Erie, PA), Dymax (Warrendale and Zelienople, PA); Addition of Subcontractors: Sterigenics US (Queensbury, NY), Sterigenics Belgium (Liege, Belgium), Sterigenics Germany (Wiesbaden, Germany), Sterigenics (Thailand) Ltd (Rayong, Thailand), Synergy Health Ireland Ltd (Offaly, Ireland), Synergy Health Westport Ltd (Mayo, Ireland), SteriTech, Inc (Salinas, PR); From certificate scope: removal of Vascular Prostheses, Pouches, Delivery System Products, High Frequency Electronic Power Supplies, Saline Injector, and clarify Class Is scope from "devices to be used in biopsy procedures" to "breast biopsy needle guides, breast biopsy distance rings"; From product table: remove Rival PTA dilation catheter (CE 556780), remove Trademark names, and modify product table entries to match device subgroups in certificate scope.

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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.

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

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