Bard Peripheral Vascular, Inc.
C. R. Bard, Inc.
1625 West 3rd Street
Tempe, AZ 85281
USA
Tel: (800) 321-4254
(480) 894-9515
Fax: (480) 966-7062

DECLARATION OF CONFORMITY

Medical Devices

Manufacturer: **Bard Peripheral Vascular, Inc.**
1625 West 3rd Street
Tempe, AZ 85281
USA

The manufacturer (Bard Peripheral Vascular, Inc.) is exclusively responsible for this Declaration of Conformity.

Product Family: **UltraClip® II Breast Tissue Markers**
UltraClip® Dual Trigger Breast Tissue Markers

Product Classification: **Class IIb**

Classification Rule: **Medical Device Directive 93/42/EEC, Annex IX, Rule 8**

The undersigned hereby declares that the medical device(s) specified in Appendix A conform to the Essential Requirements listed in Annex I of the Medical Device Directive 93/42/EEC as amended by 2007/47/EC. The conformity assessment complies with Annex II (excluding Section 4) of the Medical Device Directive 93/42/EEC as amended 2007/47/EC.

This declaration is supported by:

- EC quality system approval statement, Medical Device Directive 93/42/EEC, Annex II, Section 3.2

Certificate No.	:	**CE No. 01467**
Issued By	:	**British Standards Institution**
Notified Body No.	:	**2797**
EU Authorized Representative	:	**Becton Dickinson Ireland Limited** **Donore Road, Drogheda** **A92 YW26** **Co. Louth, Ireland**

DocuSigned by:
Jennifer Logvin
Signer Name: Jennifer Logvin
Signing Reason: I approve this document
Signing Time: 24-Jun-2022 | 7:26:43 PM EDT
9E5E5FBBA3774C2D811382488D5D71C2

Date

Jennifer Logvin
Vice President, Regulatory Affairs

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APPENDIX A

PRODUCT MATRIX

This Declaration of Conformity covers UltraClip® II Breast Tissue Markers and UltraClip® Dual Trigger Breast Tissue Markers of the following item numbers:

UltraClip® II Breast Tissue Markers

Item Number	Product Name	Dimensions
861017	UltraClip® II Breast Tissue Markers	17g x 10 cm
861217	UltraClip® II Breast Tissue Markers	17g x 12 cm
862017	UltraClip® II Breast Tissue Markers	17g x 10 cm
863017	UltraClip® II Breast Tissue Markers	17g x 10 cm
864017	UltraClip® II Breast Tissue Markers	17g x 10 cm
865017	UltraClip® II Breast Tissue Markers	17g x 10 cm
865517	UltraClip® II Breast Tissue Markers	17g x 15 cm

UltraClip® Dual Trigger Breast Tissue Markers

Item Number	Product Name	Dimensions
862017D	UltraClip® Dual Trigger Breast Tissue Marker	17g x 10 cm
862017DL	UltraClip® Dual Trigger Breast Tissue Marker	17g x 12 cm
863017D	UltraClip® Dual Trigger Breast Tissue Marker	17g x 10 cm
863017DL	UltraClip® Dual Trigger Breast Tissue Marker	17g x 12 cm
864017D	UltraClip® Dual Trigger Breast Tissue Marker	17g x 10 cm
864017DL	UltraClip® Dual Trigger Breast Tissue Marker	17g x 12 cm
866017D	UltraClip® Dual Trigger Breast Tissue Marker	17g x 10 cm
867017D	UltraClip® Dual Trigger Breast Tissue Marker	17g x 10 cm

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HISTORY OF DECLARATION OF CONFORMITY FOR

Product Family: **UltraClip® II Breast Tissue Markers**
UltraClip® Dual Trigger Breast Tissue Markers

Revision	Date	Description of Change
0	20 Jan 2017	Introduction of Revision Control as per SOPR0700140 Rev. 18. Revised Declaration of Conformity in accordance with MDD 93/42/EEC as amended by 2007/47/EC.
1	12 March 2019	Update to new Notified Body Number and EU Authorized Representative address.
2	24 June 2022	Update to Authorized Representative address to reflect change to Becton Dickinson Ireland Limited.

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: **2021-04-07** Expiry Date: **2024-05-26**

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Certificate No: CE 01467

Certificate Scope:

The design, manufacture and final inspection of ePTFE Vascular Grafts with and without carbon, 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.

First Issued: **1996-12-05** Date: **2021-04-07** Expiry Date: **2024-05-26**

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Supplementary Information to CE 01467

Issued To:

Bard Peripheral Vascular Inc
Trading as C.R. Bard Inc
1625 West 3rd Street
Tempe
Arizona
85281
USA

Number	Device Name	Intended purpose per IFU
Class III		
---	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

First Issued: **1996-12-05** Date: **2021-04-07** Expiry Date: **2024-05-26**

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 01467

Issued To:

Bard Peripheral Vascular Inc
Trading as C.R. Bard Inc
1625 West 3rd Street
Tempe
Arizona
85281
USA

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.
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.

First Issued: **1996-12-05** Date: **2021-04-07** Expiry Date: **2024-05-26**

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 01467

Issued To:

Bard Peripheral Vascular Inc
Trading as C.R. Bard Inc
1625 West 3rd Street
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Class IIa		
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	---
Class Is		
MD 0106	Breast Biopsy Needle Guides	---
MD 0106	Breast Biopsy Distance Rings	---
Class Im/Is		
MD 0104	Inflation Devices	---

First Issued: **1996-12-05** Date: **2021-04-07** Expiry Date: **2024-05-26**

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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:

Certificate No:	**CE 01467**
Date:	**2021-04-07**
Issued To:	**Bard Peripheral Vascular Inc** **Trading as C.R. Bard Inc** **1625 West 3rd Street** **Tempe** **Arizona** **85281** **USA**

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

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Date:	**2021-04-07**
Issued To:	**Bard Peripheral Vascular Inc** **Trading as C.R. Bard Inc** **1625 West 3rd Street** **Tempe** **Arizona** **85281** **USA**

Subcontractor:	**Service(s) supplied**
BD Caribe Ltd. Road 31 Km.24.3 Juncos, PR 00777-4010 Puerto Rico	**Manufacture**
Becton Dickinson Ireland Limited Donore Road Drogheda A92 YW26 Co. Louth Ireland	**EU Representative**
Biomerics FMI 1605 Enterprise Street Athens Texas 75751 USA	**Manufacture**

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

List of Significant Subcontractors

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Certificate No:	**CE 01467**
Date:	**2021-04-07**
Issued To:	**Bard Peripheral Vascular Inc** **Trading as C.R. Bard Inc** **1625 West 3rd Street** **Tempe** **Arizona** **85281** **USA**

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

List of Significant Subcontractors

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Certificate No:	**CE 01467**
Date:	**2021-04-07**
Issued To:	**Bard Peripheral Vascular Inc** **Trading as C.R. Bard Inc** **1625 West 3rd Street** **Tempe** **Arizona** **85281** **USA**

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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EC Certificate - Full Quality Assurance System

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:

Certificate No:	**CE 01467**
Date:	**2021-04-07**
Issued To:	**Bard Peripheral Vascular Inc** **Trading as C.R. Bard Inc** **1625 West 3rd Street** **Tempe** **Arizona** **85281** **USA**

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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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:

Certificate No:	**CE 01467**
Date:	**2021-04-07**
Issued To:	**Bard Peripheral Vascular Inc** **Trading as C.R. Bard Inc** **1625 West 3rd Street** **Tempe** **Arizona** **85281** **USA**

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

List of Significant Subcontractors

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Certificate No:	**CE 01467**
Date:	**2021-04-07**
Issued To:	**Bard Peripheral Vascular Inc** **Trading as C.R. Bard Inc** **1625 West 3rd Street** **Tempe** **Arizona** **85281** **USA**

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**
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**
Spectra Medical Devices, Inc. 260-F&H Fordham Road Wilmington Massachusetts 01887 USA	**Manufacture**

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

List of Significant Subcontractors

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Certificate No:	**CE 01467**
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Issued To:	**Bard Peripheral Vascular Inc** **Trading as C.R. Bard Inc** **1625 West 3rd Street** **Tempe** **Arizona** **85281** **USA**

Subcontractor:	**Service(s) supplied**
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**
Sterigenics Germany GmbH Kasteler Straße 45 65203 Wiesbaden Germany	**ETO Sterilization**

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

List of Significant Subcontractors

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Certificate No:	**CE 01467**
Date:	**2021-04-07**
Issued To:	**Bard Peripheral Vascular Inc** **Trading as C.R. Bard Inc** **1625 West 3rd Street** **Tempe** **Arizona** **85281** **USA**

Subcontractor:	**Service(s) supplied**
Sterigenics US, LLC 10811 Withers Cove Park Drive Charlotte North Carolina 28278 USA	**Radiation (Gamma Sterilization)**
Sterigenics US, LLC 10821 Withers Cove Park Drive Charlotte North Carolina 28278 USA	**ETO Sterilization**
Sterigenics US, LLC 344 Bonnie Circle Corona California 92880 USA	**Radiation (Gamma Sterilization)**

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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:

Certificate No:	**CE 01467**
Date:	**2021-04-07**
Issued To:	**Bard Peripheral Vascular Inc** **Trading as C.R. Bard Inc** **1625 West 3rd Street** **Tempe** **Arizona** **85281** **USA**

Subcontractor:	**Service(s) supplied**
Sterigenics US, LLC 84 Park Road Queensbury New York 12804 USA	**ETO Sterilization**
Steritec, Inc. PO Box 1969 1705 Enterprise Street Athens Texas 75751 USA	**ETO Sterilization**
Steri-Tech, Inc. Road 701 KM 0.7 Salinas Industrial Park 00751 Salinas Puerto Rico	**ETO Sterilization**

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

List of Significant Subcontractors

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Certificate No:	**CE 01467**
Date:	**2021-04-07**
Issued To:	**Bard Peripheral Vascular Inc** **Trading as C.R. Bard Inc** **1625 West 3rd Street** **Tempe** **Arizona** **85281** **USA**

Subcontractor:	**Service(s) supplied**
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)**
Synergy Health Westport Ltd Lodge Road Westport County Mayo Ireland	**Radiation (Gamma Sterilization)**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 01467**

Date: **2021-04-07**

Issued To: **Bard Peripheral Vascular Inc**
Trading as C.R. Bard Inc
1625 West 3rd Street
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Arizona
85281
USA

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'

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 01467**
Date: **2021-04-07**
Issued To: **Bard Peripheral Vascular Inc**
Trading as C.R. Bard Inc
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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.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 01467**

Date: **2021-04-07**

Issued To: **Bard Peripheral Vascular Inc**
Trading as C.R. Bard Inc
1625 West 3rd Street
Tempe
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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.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 01467**

Date: **2021-04-07**

Issued To: **Bard Peripheral Vascular Inc**
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Tempe
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USA

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.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 01467**

Date: **2021-04-07**

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

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.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 01467**

Date: **2021-04-07**

Issued To: **Bard Peripheral Vascular Inc**
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1625 West 3rd Street
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Date	Reference Number	Action
03 August 2020	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.
07 April 2021	3393493	Reduction of scope to remove Balloon Expandable Stents. Clarification of scope to include 'final inspection' and remove 'development'. Update to products table in supplementary information section to remove Balloon Expandable Stents. Removal of subcontractor MeKo (Hannover, Germany).

EC Certificate - Full Quality Assurance System Certificate History

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Date: **2021-04-07**

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

Date	Reference Number	Action
Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3		
16 June 2022	3604160	Change in EU Representative from "BD Switzerland Sarl" to "Becton Dickinson Ireland Limited". Scope reduced to remove "Vena Cava Filters, Filter Retrieval Devices". The Class III Simon Nitinol Filter with the SNF/SL Delivery System and Denali Filter System, and RC15 Recovery Cone Removal System are removed from the device table.

Inspiring trust for a more resilient world.

16 June 2022

Bard Peripheral Vascular Inc
Trading as C.R. Bard Inc
1625 West 3rd Street
Tempe
Arizona
85281
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 01467	93/42/EEC Annex II excluding Section 4	3604160	Change in EU Representative from "BD Switzerland Sarl" to "Becton Dickinson Ireland Limited". Scope reduced to remove "Vena Cava Filters, Filter Retrieval Devices". The Class III Simon Nitinol Filter with the SNF/SL Delivery System and Denali Filter System, and RC15 Recovery Cone Removal System are removed from the device table.

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,

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