

# EC Certificate - Full Quality Assurance System

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

**No.****CE 566541**

## Issued To:

**Davol, Inc.  
Subsidiary of C.R. Bard, Inc.  
100 Crossings Boulevard  
Warwick  
Rhode Island  
02886  
USA**

In respect of:

**The design, development and manufacture of fully absorbable, partially absorbable, and non-absorbable synthetic meshes and porcine collagen meshes for soft tissue repair and reconstruction, with or without mesh positioning system; absorbable and non-absorbable fixation devices for mesh fixation and soft tissue approximation; bovine collagen haemostasis devices and associated delivery system; absorbable polysaccharide based clotting beads and associated manual applicators for interoperative surgical applications. Those aspects of Annex II related to securing and maintaining sterility in the manufacture of inflation assembly sets.**

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: **2010-11-05**Date: **2021-02-05**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.

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## Supplementary Information to CE 566541

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Number	Device Name	Intended purpose per IFU
<b>Class III</b>		
---	Sepramesh IP	See CE 566556
---	Avitene MicroFibrillar Collagen Hemostat	See CE 566551
---	Avitene Ultrafoam Collagen Sponge	See CE 566551
---	Avitene Non-Woven Web	See CE 566551
---	SorbaFix Absorbable Fixation System	See CE 566554
---	Ventralight ST Mesh	See CE 570168
---	Ventralight ST with Echo PS	See CE 570168
---	Ventralight ST with Echo 2 PS	See CE 570168
---	Ventrex ST	See CE 576029
---	Ventrio ST	See CE 576031
---	XenMatrix	See CE 581769
---	Arista AH	See CE 623432
---	Phasix Mesh	See CE 623403
---	Phasix ST Mesh	See CE 623403
---	OptiFix Absorbable Fixation System	See CE 636517
---	OptiFix Open Absorbable Fixation System	See CE 636517

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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 IIb</b>		
MD 0204	Non-absorbable Synthetic Mesh	Indicated for use in reinforcement of soft tissue in the repair of hernia, chest wall defects, and groin hernia defects.
MD 0204	Partially absorbable synthetic mesh	Indicated for use in the reinforcement of soft tissue deficiencies in the repair of ventral, incisional and umbilical hernias.
MD 0204	Permanent Fixation System	Used in approximation of soft tissue and fixation of surgical mesh to tissues during open or laparoscopic surgical procedures in ventral and inguinal hernia repair.
<b>Class IIa</b>		
MD 0106	Manual applicators for interoperative surgical applications	---
<b>Class Is</b>		
MD 0106	Inflation assembly sets	---

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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:

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**USA**

<b>Subcontractor:</b>	<b>Service(s) supplied</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>
Bard Shannon Ltd San Geronimo Industrial Park Lot #1 Road #3, km 79.7 Humacao 00791 Puerto Rico	<b>Manufacture</b>

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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
BD Switzerland Sàrl Terre Bonne Park - A4 Route de Crassier 17 1262 Eysins Switzerland	<b>EU Representative</b>
Davol Delran 1822 Underwood Blvd Delran New Jersey 08075 USA	<b>Crucial Supplier</b>
Davol, Inc. 160 New Boston Street Woburn Massachusetts 01801 USA	<b>Dry Heat Sterilization (Thermic sterilization with dry heat)                      Manufacture</b>

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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Devro-Pty Ltd. 139 Sydney Road Bathurst NSW 2795 Australia	<b>Animal Tissues / Derivatives</b>
Isomedix Operations, Inc. North Facility 1880 Industrial Drive Libertyville Illinois 60048 USA	<b>Radiation (Gamma Sterilization)</b>
Isomedix Operations, Inc. 435 Whitney Street Northborough Massachusetts 01532 USA	<b>Radiation (Gamma Sterilization)</b>

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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Isomedix Operations, Inc. 2500 Commerce Drive Libertyville Illinois 60048 USA	<b>Radiation (Gamma Sterilization)</b>
Lyophilization Services of New England, Inc. One Sundial Avenue, Suite 112 Manchester NH 03103 USA	<b>Manufacture</b>
Pine Ridge Farms 1800 SE Maury St. Des Moines Iowa 50317 USA	<b>Animal Tissues / Derivatives</b>

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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
pK Chemical Kobenhavnsvej, Koege DK-4600 Denmark	<b>Crucial Supplier</b>
Professional Contract Sterilization Inc 40 Myles Standish Boulevard Taunton Massachusetts 02780-1026 USA	<b>ETO Sterilization</b>
Sterigenics US LLC 7695 Formula Place San Diego CA 92121 USA	<b>Radiation (E Beam Sterilization)</b>

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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Steris Isomedix Puerto Rico LLC State Road 690 KM 1.7 Barrio Sabana Hoyos Vega Alta 00692 Puerto Rico USA	<b>Radiation (Gamma Sterilization)</b>
Steri-Tech, Inc. Road 701 KM 0.7 Salinas Industrial Park Salinas 00751 Puerto Rico	<b>ETO Sterilization</b>
Surgical Technologies, Incorporated Also trading as McLean Medical & Scientific 292 E. Lafayette Frontage Road St Paul Minnesota 55107 USA	<b>Manufacture</b>

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**USA**

**Subcontractor:**

**Service(s) supplied**

Tepha Inc.  
99 Hayden Ave.,  
Suite 360  
Lexington  
Massachusetts  
02421  
USA

**Manufacture**

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# EC Certificate - Full Quality Assurance System Certificate History

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Date	Reference Number	Action
05 November 2010	7574232	First issue, transfer from another Notified Body (KEMA 66041CE01, KEMA 66041CE05, KEMA 66041CE06 and KEMA 66041CE07).
20 October 2011	7759611	Identification of sterilization method for significant subcontractors. Change of address for significant subcontractor Spear Products. Certificate renewal.
01 May 2012	7828440 7821033	Change in scope to add mesh positioning system. Addition of significant subcontractors Pine Ridge Farms LLC, Brennen Medical, LLC and RSI Leasing, Inc. dba Sterigenics.
13 March 2015	7945822	Removal of re-usable and disposable electro-surgical probes for suction irrigation and cutting during laparoscopic procedures and discontinued endoscopic suturing kit for gastroesophageal reflux disease from certificate scope. Removal of significant subcontractors Brennen Medical, LLC, ATC Technologies Inc and CR Bard Glens Falls. Correction to post code of significant subcontractor Devro Pty Ltd from 2794 to 2795.

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Date	Reference Number	Action
31 March 2015	8254953	Change scope to add fully resorbable meshes, change porcine collagen prostheses to porcine collagen meshes, and add of soft tissue reconstruction; add new subcontractor (Tepha) and correct address for ETO sterilization subcontractor (C.R. Bard - Madison, GA).
17 August 2015	8255177	Extension to scope to add polysaccharide based clotting beads. Addition of significant subcontractors Surgical Technologies, Inc, Magle AB and Steris Isomedix Services, IL 60048 (1880 Industrial Drive and 2500 Commerce Drive locations).
26 October 2016	8585478	Extension of scope to include Class I Sterile inflation assembly sets. Removal of significant subcontractors Magle AB and Spear Products. Addition of significant subcontractors Primo Medical Group Inc, 02072 USA, Primo Medical Group Inc, 02379 USA and pK Chemical. Certificate Renewal.
20 December 2016	8648421	Addition of Delran as a crucial supplier.

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Date	Reference Number	Action
28 February 2019	7781541	Traceable to NB 0086. Administrative Subcontractor Service wording update from 'Animal Substances' to 'Animal Tissue/ Derivatives' for Subcontractor Devro-Pty Ltd & Pine Ridge Farms.
16 October 2019	3073365	Update of Authorized representative to BD Switzerland Sàrl.
Current	9788950	Certificate renewal. Removal of Bridger Biomed and Primo Medical Group at 375 West Street, West Bridgewater. Administrative update to add supplementary table per MDP4500. Name change for Steris Isomedix, RSI Leasing Inc dba Sterigenics to Isomedix Operations, Inc. Subcontractor name change for C.R. Bard sterilization facilities. Address and name update for Isomedix Operations, Inc. North Facility 1880 Industrial Drive, Libertyville, Illinois. Name change for Steris Isomedix Services, Inc to Isomedix Operations, Inc. at Northborough, MA and Libertyville, IL

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Date	Reference Number	Action
		Name or address update for Bard Regional Sterilization Facilities, Steri-Tech, Surgical Technologies and Tepha Inc to align with subcontractor's ISO 13485 certificates Name update for Bard Shannon Ltd to remove Bard Puerto Rico Operation Scope reduction of 'topical use and post-op application' for ENT products