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EC Certificate - Full Quality Assurance System

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

No.	**CE 668274**
Issued To:	**W.L. Gore & Associates, Inc.** **1505 N. Fourth Street** **Flagstaff** **Arizona** **86004** **USA**

In respect of:

Design, Development, and Manufacture of sterile heparin-coated and uncoated vascular endoprosthesis and delivery systems, intrahepatic and biliary endoprosthesis and delivery systems, heparin coated vascular stents and delivery systems, heparin-coated and uncoated vascular grafts, introducer sheaths, intravascular balloon catheters, septal defect closure devices, pericardial membranes, cardiovascular patches, medicated and non-medicated non-absorbable soft tissue patches, absorbable soft tissue patches, suture with or without pledgets, absorbable staple line reinforcement material.

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

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2017-04-26** Date: **2020-07-08** Expiry Date: **2024-05-26**

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Supplementary Information to CE 668274

Issued To: **W.L. Gore & Associates, Inc.**
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Number	Device Name	Intended purpose per IFU
Class III		
---	GORE® DUALMESH® PLUS Biomaterial	See CE 668275
---	GORE® BIO-A® Tissue Reinforcement	See CE 668277
---	GORE® PRECLUDE® Pericardial Membrane	See CE 668279
---	GORE® ACUSEAL Cardiovascular Patch GORE-TEX® Cardiovascular Patch	See CE 668283
---	Intravascular low pressure compliance molding and occlusion balloon catheters	See CE 668284
---	GORE-TEX® Suture, with or without GORE® Pledgets	See CE 668285
---	GORE-TEX® Vascular Graft GORE® INTERING® Vascular Grafts	See CE 668286
---	GORE® TIGRIS® Vascular Stent	See CE 668287
---	GORE® TAG® Thoracic Endoprosthesis	See CE 668288
---	GORE® ACUSEAL Vascular Graft	See CE 668291
---	GORE® PROPATEN® Vascular Graft	See CE 668292
---	GORE® CARDIOFORM Septal Occluder	See CE 668293
---	GORE® VIABAHN® Endoprosthesis with PROPATEN Bioactive Surface	See CE 668295

First Issued: **2017-04-26** Date: **2020-07-08** Expiry Date: **2024-05-26**

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Number	Device Name	Intended purpose per IFU
---	GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement– configured for Circular Staplers	See CE 668296
---	GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement– configured for Endoscopic Staplers	See CE 668297
---	GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis	See CE 668299
---	GORE® EXCLUDER® AAA Endoprosthesis	See CE 668300
---	GORE® EXCLUDER® Iliac Branch Endoprosthesis	See CE 668301
---	GORE® EXCLUDER® Conformable AAA Endoprosthesis	See CE 668302
---	GORE® CARDIOFORM ASD Occluder	See CE 711889
---	GORE® SYNECOR Intraperitoneal Biomaterial	See CE 715434

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Number	Device Name	Intended purpose per IFU
Class IIb		
60300	GORE® DUALMESH® Biomaterial	The GORE® DUALMESH® Biomaterial is indicated for use in the reconstruction of ventral / incisional and diaphragmatic hernias and chest wall soft tissue deficiencies.
47932	GORE® VIABAHN® Endoprosthesis	The GORE® VIABAHN® Endoprosthesis is intended for endovascular grafting of peripheral arteries. The GORE® VIABAHN® Endoprosthesis is also indicated for improving blood flow in symptomatic obstructions of peripheral veins.
43566	GORE® VIABIL® Biliary Endoprosthesis and delivery system catheter GORE®VIABIL® Short Wire Biliary Endoprosthesis and delivery system	Removable Configurations: The GORE® VIABIL® Biliary Endoprosthesis is indicated for the treatment of benign and malignant biliary strictures and can be removed from such strictures for up to one year post implant. Non-Removable Configurations: The GORE® VIABIL® Biliary Endoprosthesis is intended for palliation of malignant strictures in the biliary tree.

First Issued: **2017-04-26** Date: **2020-07-08** Expiry Date: **2024-05-26**

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Number	Device Name	Intended purpose per IFU
58043	GORE® VIATORR® TIPS Endoprosthesis with / without Controlled Expansion, extender and delivery system catheter	The GORE® VIATORR® TIPS Endoprosthesis is indicated for use in the treatment of portal hypertension and its complications such as: variceal bleeding refractory to, or intolerant of, conventional therapies, inaccessible varices, gastropathy, refractory ascites, and/or hepatic hydrothorax.
60300	GORE-TEX® Soft Tissue Patch	The GORE-TEX® Soft Tissue Patch is indicated for use in the reconstruction of diaphragmatic hernias and chest wall soft tissue deficiencies. 1 mm and 2 mm thicknesses are available. For full thickness or segmental wall defects, use of the GORE-TEX ® Soft Tissue Patch 2 mm should be considered.
Class IIa		
MD0106	GORE® DrySeal Flex Introducer Sheath	---

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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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Subcontractor:	Service(s) supplied
Advance Medical Designs 1241 Atlanta Industrial Drive Marietta Georgia 30066 USA	**Control of Sterilization** **Manufacture** **Packaging**
Bavaria Medizin Technologie GmbH Argelsrieder Feld 8 Wessling 82234 Germany	**Manufacture**
Carmeda AB Kanalvägen 3B 194 61 Upplands Väsby Sweden	**Crucial Supplier** **Manufacture**

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Subcontractor:	**Service(s) supplied**
Centurion Medical Products Corporation 3173 East 43rd Street Yuma Arizona 85365 USA	**ETO Sterilization**
Creagh Medical Ltd. IDA Business Park Ballinasloe Co Galway H53 K8P4 Ireland	**Control of Sterilization** **Manufacture**
Creganna Medical Parkmore West Galway Ireland	**Control of Sterilization** **Manufacture**

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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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Subcontractor:	**Service(s) supplied**
DF Goldsmith 909 Pinter Avenue Evanston Illinois 60202 USA	**Crucial Supplier**
George UHE Company 230 West Parkway, Suite 5 Pompton Plains New Jersey 07444 USA	**Crucial Supplier**
Isomedix Operations, Inc. North Facility 1880 Industrial Drive Libertyville Illinois 60048 USA	**Radiation (Gamma Sterilization)**

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Subcontractor:	**Service(s) supplied**
MEKO Laserstrahl-Materialbearbeitungen Im Kirchenfelde 12-14 Sarstedt Hannover 31157 Germany	**Crucial Supplier**
Norman Noble, Inc. 5507 Avion Park Drive Highland Heights Ohio 44143 USA	**Crucial Supplier**
Scientific Protein Laboratories LLC 700 East Main Street Waunakee Wisconsin 53597 USA	**Crucial Supplier**

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Subcontractor:	Service(s) supplied
Sterigenics US, LLC 4900 Gifford Avenue Los Angeles California 90058 USA	**ETO Sterilization**
Sterigenics US, LLC 84 Park Road Queensbury New York 12804 USA	**ETO Sterilization**
Sterigenics US, LLC 10811 Withers Cove Park Dr Charlotte North Carolina 28278 USA	**Radiation (Gamma Sterilization)**

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Subcontractor:	**Service(s) supplied**
Sterigenics US, LLC 5725 W. Harold Gatty Drive Salt Lake City Utah 84116 USA	**ETO Sterilization**
Sterigenics US, LLC 344 Bonnie Circle Corona California 92880 USA	**Radiation (Gamma Sterilization)**
Sterilization Services of Georgia 6005 Boatrock Boulevard Atlanta Georgia 30336 USA	**ETO Sterilization**

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Subcontractor:	Service(s) supplied
Surgical Specialities Corporation 9993 Marconi Drive San Diego California 92154 USA	**Crucial Supplier**
Synergy Health Ireland Ltd (Synergy Health - AST - Ireland) IDA Business & Technology Park Tullamore, Co. Offaly Ireland	**ETO Sterilization**
Synergy Health Sterilization UK Ltd. (Synergy Health - AST - Thorne) 1 Alpha Court Capitol Park Thorne Doncaster DN8 5TZ UK	**ETO Sterilization**

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Subcontractor:	Service(s) supplied
The Secant Group, LLC. 195 O'Neill Drive Quakertown Pennsylvania 18951 USA	**Crucial Supplier**
Trelleborg Sealing Solutions Delano, LLC 740 Seventh Street South Delano Minnesota 55328 USA	**Crucial Supplier**
W.L. Gore & Associates B.V Ringbaan-Oost 152 A 5013 CE Tilburg Netherlands	**EU Representative**

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Subcontractor:	Service(s) supplied
W.L. Gore & Associates B.V. European Warehouse Support Doctor Paul Janssenweg 150 5026 RH Tilburg The Netherlands	**Manufacture**
W.L. Gore & Associates, Inc GCT-EM 501 Vieve's Way Elkton Maryland 21921 USA	**Crucial Supplier**
W.L. Gore & Associates, Inc GCT-CH 2401 Singerly Road Elkton Maryland 21921 USA	**Crucial Supplier**

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Subcontractor:	Service(s) supplied
W.L. Gore & Associates, Inc Appleton Central 301 Airport Road Elkton Maryland 21921 USA	**Design** **Manufacture** **Moist Heat Sterilization**
W.L. Gore & Associates, Inc. Phoenix 3 32320 North Valley Parkway Phoenix Arizona 85085 USA	**Manufacture** **Moist Heat Sterilization**

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Subcontractor:	Service(s) supplied
W.L. Gore & Associates, Inc. Silicon Valley 2890 De La Cruz Blvd. Santa Clara California 95050 USA	**Design Manufacture**
W.L. Gore & Associates, Inc. Medical Central 1500 N. Fourth Street Flagstaff Arizona 86004 USA	**Design Manufacture Moist Heat Sterilization**

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Subcontractor:	Service(s) supplied
W.L. Gore & Associates, Inc. Kendrick Peak 4250 W. Kiltie Lane Flagstaff Arizona 86005 USA	**Design Manufacture**
W.L. Gore & Associates, Inc. Woody Springs 3450 W. Kiltie Lane Flagstaff Arizona 86005 USA	**Design Manufacture**

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Subcontractor:	**Service(s) supplied**
W.L. Gore & Associates, Inc. Phoenix 2 32470 North Valley Parkway Phoenix Arizona 85085 USA	**Design** **Manufacture**
W.L. Gore & Associates, Inc. Phoenix 1 32360 North Valley Parkway Phoenix Arizona 85085 USA	**Design** **Manufacture**

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Subcontractor:	**Service(s) supplied**
W.L. Gore & Associates, Inc. Fisher Point 4000 W. Kiltie Lane Flagstaff Arizona 86005 USA	**Manufacture**
W.L. Gore & Associates, Inc. Echo Ridge 3250 W. Kiltie Lane Flagstaff Arizona 86005 USA	**Design** **Manufacture**

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EC Certificate - Full Quality Assurance System
Certificate History

Certificate No: **CE 668274**

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Date	Reference Number	Action
26 April 2017	8679283	First Issue. Transfer from another Notified Body.
08 June 2017	8733724	Transfer from another notified body of the following device families: GORE® TIGRIS® Vascular Stent, GORE® Embolic Filter, GORE® Carotid Stent, GORE® DrySeal Sheath, GORE® DrySeal Flex Sheath, and GORE® VIABIL® Biliary Endoprosthesis and delivery system catheter. Addition of multiple significant subcontractors and crucial suppliers associated with transferring device families as listed.

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Date	Reference Number	Action
14 July 2017	8733725	Transfer from another notified body of the following device families: GORE® DUALMESH® PLUS Biomaterial, GORE® DUALMESH® Biomaterial, GORE® MYCROMESH® Biomaterial, GORE-TEX® Soft Tissue Patch, GORE® BIO-A® Tissue Reinforcement, GORE® BIO-A® Hernia Plug, GORE® PRECLUDE® Pericardial Membrane, GORE® ACUSEAL Cardiovascular Patch, GORE-TEX® Cardiovascular Patch, GORE® TRI-LOBE Balloon Catheter, GORE-TEX® Suture, GORE-TEX® and GORE-INTERING® Vascular Grafts, GORE® HYBRID Vascular Graft, GORE® ACUSEAL Vascular Graft, GORE® PROPATEN® Vascular Graft, GORE® CARDIOFORM Septal Occluder, GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement for Circular Staplers, and GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement for Endoscopic Staplers. Addition of multiple significant subcontractors and crucial suppliers associated with transferring device families as listed.
10 November 2017	8792894 8847088	Transfer from another notified body of the following device families: GORE® VIABAHN® Endoprosthesis with PROPATEN® Bioactive Surface, GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis. Addition of significant subcontractors Bavaria Medizin Technologie and Meko Laserstrahl-Materialbearbeitungen. Certificate Renewal. Removal of W.L. Gore & Associates Sunnyvale facility.

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Date	Reference Number	Action
03 January 2018	8868400	Review of the Risk Management Process and Reports update required after the certificate transfer. Add Moist Heat Sterilization for Appleton Central site.
02 August 2018	9625027	Addition of subcontractor Creagh Medical Ltd.
08 February 2019	8742843	Traceable to NB 0086.
16 May 2019	9720365	Remove heparin coated embolic filters and hernia plugs from the scope. Remove W.L. Gore & Associates U.K Ltd site in Dundee, Scotland for the certificate. Added W.L Gore & Associates B.V as the EU Representative. Addition of Moist Heat Sterilization to the activities of Phoenix 3. Addition of subcontractor Synergy Health Sterilization UK Ltd
15 January 2020	3086143	Addition of subcontractor W.L. Gore & Associates, Inc. Fisher Point, Flagstaff, AZ after being mistakenly removed in the previous update. Addition of subcontractor W.L. Gore & Associates, Inc. B.V. European Warehouse Support site due to expansion of ISO 13485 covered activities and required audits. Addition of subcontractor Sterigenics US, LLC Queensbury, NY for ETO Sterilization. Removal of subcontractor Norman Noble, Highlands Heights, OH. Removal of Crucial Supplier Lake Region Medical, Chaska, MN.

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Date	Reference Number	Action
10 June 2020	3119394	Certificate Renewal. Addition of product supplementary information table. Addition of subcontractor 'Norman Noble, Inc., 5507 Avion Park Drive, Highland Heights, Ohio 44143, USA' after being mistakenly removed in the previous update. Norman Noble reinstated address updated from 'Highlands Heights' to 'Highland Heights'. MEKO Laserstrahl-Materialbearbeitungen activity updated from 'Manufacture' to 'crucial supplier'. Carmeda AB activity updated from 'crucial supplier' to 'manufacture, crucial supplier'. SIL-PRO name changed to 'Trelleborg Sealing Solutions Delano, LLC' and address format updated from '740 Seventh Street, South Delano' to '740 Seventh Street South, Delano' W.L. Gore & Associates (Silicon Valley) activity updated from 'manufacture' to 'design, manufacture'. Subcontractor's name change from 'Cherry Hill' to 'GCT-CH' & from 'Elk Mills 1' to 'GCT-EM'. Correct subcontractor's name typo (W.L. Gore & Associates, Inc. – Kendrick Peak, Arizona). Update to subcontractor's name and/or address in line with vendors' certificates (Carmeda AB, Centurion Medical Products Corporation, Creagh Medical Ltd, Sterigenics US, LLC (W. Harold Gatty Drive, SLC), Sterilization services of Georgia). Correction to Certificate History to reinstate entry 8847088, 10 November 2017, which had been inadvertently removed in previous revisions.

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Date	Reference Number	Action
Current	3253294	Addition of GORE® SYNECOR Intraperitoneal Biomaterial - CE 715434 to product table. Addition of crucial supplier The Secant Group, LLC, Quakertown, Pennsylvania.

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