

# EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

## MDR 731888 R000

**Manufacturer:** Davol Inc., Subsidiary of C.R. Bard, Inc.

**Address:**

100 Crossings Boulevard  
Warwick  
Rhode Island  
02886  
USA

**Single Registration Number:** US-MF-000017971

**EU Authorised Representative:** Becton Dickinson Ireland Limited

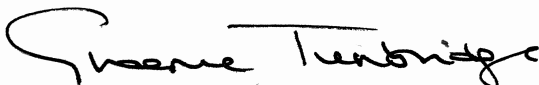
**Address:**

Donore Road  
Drogheda  
Co. Louth  
A92 YW26  
Ireland

**Scope:** See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):



Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: **2021-09-09**

Current Issue Date: **2024-07-03**

Starting Validity Date: **2024-07-03**

Expiry Date: **2026-09-08**

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### Device Schedule: Class III and Class IIb devices

Class III, Implantable	Intended purpose
Ventralex™ ST Hernia Patch	See MDR 731914
Ventrio™ ST Hernia Patch	See MDR 731915
3DMax™ Mesh	See MDR 747742
3DMax™ Light Mesh	See MDR 747746
3DMax™ MID Anatomical Mesh	See MDR 747746
Arista™ AH Absorbable Haemostatic Particles	See MDR 731916
Bard® Mesh	See MDR 785984
Bard® Mesh Pre-shaped	See MDR 785985
Bard® Soft Mesh	See MDR 785987
Bard® Soft Mesh Pre-Shaped	See MDR 785987
PerFix™ Plug	See MDR 785986
PerFix™ Light Plug	See MDR 760226
Phasix™ Mesh	See MDR 747748
Phasix™ ST Mesh	See MDR 747749
Sorbafix™ Absorbable Fixation System	See MDR 731908
Ventralight™ ST Mesh	See MDR 731910
Ventralight™ ST with Echo PS™ Positioning System	See MDR 731912
Ventralight™ ST with Echo 2™ Positioning System	See MDR 731913
XenMatrix™ Surgical Graft; porcine Collagen-based acellular dermal matrix	See MDR 747747
Class IIb, Implantable	Intended purpose
CapSure™ Permanent Fixation System	See MDR 760228

### Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Haemostasis Applicator System	Class IIa

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### Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from [Certificate.Verification@bsigroup.com](mailto:Certificate.Verification@bsigroup.com))

Date	Reference Number	Action
2021-09-09	3253137	Issued.
2022-04-08	3539998	Supplemented – Addition of Ventralight ST, Ventralight ST with Echo PS, and Ventralight ST with Echo 2 PS devices. Addition of subcontractors for Manufacture and ETO Sterilisation.
2022-04-26	3658119	Supplemented – Addition of 3DMax™ Mesh, 3DMax™ Light Mesh, XenMatrix™ Surgical Graft, and Phasix™ Mesh devices. Amended – Addition of subcontractors for Radiation (E Beam Sterilisation) and ETO Sterilisation. Amended – Addition of crucial suppliers.
2023-01-11	3562175	Supplemented – Addition of Phasix™ ST Mesh, PerFix™ Light Plug.
2023-05-09	3895938	Supplemented – Addition of CapSure™ Permanent Fixation System Amended – Correction to 2022-04-26 history entry to correct the name from "Phasix™ ST Mesh" to "Phasix™ Mesh" and spelling correction from "3DMax™ Mash" to "3DMax™ Mesh"
2024-01-18	30003403	Supplemented – Addition of Bard® Mesh and Bard® Mesh Pre-shaped
2024-02-08	30093011	Supplemented – Addition of 3DMax MID Anatomical Mesh Amended – Administrative update to list Class III/IIb devices in device schedule in alphabetical order
2024-05-10	30107777	Supplemented – Addition of PerFix™ Plug
Current	30123386	Supplemented – Addition of Bard® Soft Mesh and Bard® Soft Mesh Pre-Shaped

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80  
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.  
A Member of the BSI Group of Companies.