

EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

MDR 731910 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

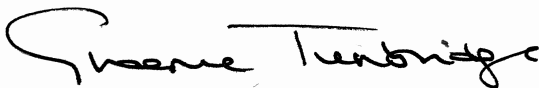
Address:

Donore Road
Drogheda
Co. Louth
A92 YW26
Ireland

Scope: See attached **Device Schedule**

On the basis of our assessment of the technical documentation in accordance with Regulation (EU) 2017/745, Annex IX Chapter II, the technical documentation meets the requirements of the Regulation. For the placing on the market of these devices an additional Annex IX Chapter I and III 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 Medical Devices

First Issued: **2022-04-08**

Date: **2022-04-08**

Expiry Date: **2027-04-07**

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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.
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Device Schedule:

Intended Purpose as per the Instructions for Use:

Indicated for use in the reconstruction of soft tissue deficiencies in the repair of ventral, incisional, and umbilical hernias.

Basic UDI-DI: 0801741EVWZHHRO9M

Type (Codes as per (EU) 2017/2185): MDN 1104

Device Name	Model	Mesh Shape	Risk Classification
Ventralight™ ST Mesh 4.5" (11.4 cm)	5954450G	Circle	Class III Implantable
Ventralight™ ST Mesh 4" x 6" (10.2 cm x 15.2 cm)	5954460G	Ellipse	
Ventralight™ ST Mesh 6" (15.2 cm)	5954600G	Circle	
Ventralight™ ST Mesh 6" x 8" (15.2 cm x 20.3 cm)	5954680G	Ellipse	
Ventralight™ ST Mesh 6" x 10" (15.2 cm x 25.4 cm)	5954610G	Oval	
Ventralight™ ST Mesh 7" x 9" (17.8 cm x 22.9 cm)	5954790G	Ellipse	
Ventralight™ ST Mesh 8" (20.3 cm)	5954800G	Circle	
Ventralight™ ST Mesh 8" x 10" (20.3 cm x 25.4 cm)	5954810G	Ellipse	
Ventralight™ ST Mesh 10" x 13" (25.4 cm x 33.0 cm)	5954113G	Ellipse	
Ventralight™ ST Mesh 12" x 14" (30.5 cm x 35.6 cm)	5954124G	Rectangle	

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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)

Date	Reference Number	Action
Current	3253187	Issued.



First Issued: **2022-04-08**

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