



## EU DECLARATION OF CONFORMITY (DoC)

<b>Manufacturer:</b>	Davol Inc., Subsidiary of C. R. Bard, Inc. 100 Crossings Blvd Warwick, R.I. 02886 USA
<b>Manufacturer SRN#:</b>	US-MF-000017971
<b>Authorized Representative:</b>	Becton Dickinson Ireland Limited Donore Road, Drogheda A92 YW26 Co. Louth, Ireland
<b>Authorized Representative SRN#:</b>	IE-AR-000007610
<b>Product:</b>	<p><b>Trade Name:</b> Ventralight™ ST Mesh – Low Profile Bioresorbable Coated Permanent Mesh for Soft Tissue Reconstruction.</p> <p><b>Intended Use:</b> Ventralight™ ST Mesh is indicated for use in the reconstruction of soft tissue deficiencies in the repair of ventral, incisional, and umbilical hernias.</p> <p><b>Intended User:</b> The Ventralight™ ST Mesh is intended to be used by surgical professionals who perform open or laparoscopic hernia repair procedures on adult patients. The device is not intended to be used by laypersons or by surgical professionals within other specialties that do not primarily include soft tissue (e.g. hernia) repair.</p> <p><b>Device Description:</b> Ventralight™ ST Low Profile Bioresorbable Coated Permanent Mesh is a dual-component (absorbable and nonabsorbable) sterile mesh designed for the reconstruction of soft tissue deficiencies in adults with ventral, incisional, or umbilical hernias. The low profile mesh facilitates laparoscopic deployment and the pre-sized shapes offer maximum ready-to-use benefits with the option of tailoring as needed.</p>

	Ventralight™ ST Mesh is co-knitted using polypropylene (PP, < 30%) and polyglycolic acid (PGA, < 35%) fibers to result in a two-sided mesh with a PP surface and a PGA surface. The mesh is coated on the PGA surface with a bioresorbable, chemically modified sodium hyaluronate (HA), carboxymethylcellulose (CMC) and polyethylene glycol (PEG) based hydrogel (PEG < 20%, HACMC, < 10%). The mesh contains D&C Violet No. 2 (<0.1%) colorant which is found in the PGA.
<b>Basic UDI-DI:</b>	0801741EVWZHHRO9M
<b>Risk Class and Rule:</b>	Annex VIII, Rule 8 (Class III)
<b>Intended Purpose</b>	<p>Ventralight™ ST Mesh is indicated for use in the reconstruction of soft tissue deficiencies in the repair of ventral, incisional, and umbilical hernias.</p> <p><b>Intended User:</b></p> <p>The Ventralight™ ST Mesh is intended to be used by surgical professionals who perform open or laparoscopic hernia repair procedures on adult patients. The device is not intended to be used by laypersons or by surgical professionals within other specialties that do not primarily include soft tissue (e.g. hernia) repair.</p>
<b>Notified Body:</b>	<p>BSI Group The Netherlands B.V.</p> <p>Say Building, John M. Keynesplein 9, 1066 EP Amsterdam</p> <p>Country: Netherlands</p> <p>Notified Body Number: 2797</p>
<p>We, as the manufacturer of the device(s) take sole responsibility for and hereby declare that the above-mentioned product(s) meet(s) the provisions of the following Directives/ Regulation(s):</p> <ul style="list-style-type: none"> <li>Regulation (EU) 2017/745 of the European Parliament and of the Council on Medical Devices</li> <li>REACH Regulation</li> </ul>	



## Conformity Assessment Route:

<input checked="" type="checkbox"/> ANNEX IX Chapter I and III – Quality management System	EC CERTIFICATE No.:731888 Certificate Expiration Date: 08 September 2026
<input checked="" type="checkbox"/> ANNEX IX Chapter II - Technical Documentation	MDR CERTIFICATE No.: 731910 Certificate Expiration Date: 07 April 2027
<input type="checkbox"/> ANNEX X Type Examination	EC CERTIFICATE No.: Certificate Expiration Date:
<input type="checkbox"/> ANNEX XI Part A Production Quality Assurance	EC CERTIFICATE No.: Certificate Expiration Date:
<input type="checkbox"/> ANNEX XI Part B Product Verification	EC CERTIFICATE No.: Certificate Expiration Date:
<input type="checkbox"/> ANNEX II & III Technical Documentation	N/A

## Common Specifications (CS):

Number: <Version/Year>	Title:	Full or Partial Application: <Justification>
N/A	N/A	N/A

Common Specifications have not been issued for this product.

## Devices Covered by this DoC:

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

**Authorised Signatory:**

<b>Name &amp; Title:</b>	Daniel Campion Vice President Regulatory Affairs
<b>On behalf of:</b>	Davol Inc., Subsidiary of C. R. Bard, Inc. 100 Crossings Blvd Warwick, RI 02886 USA
<b>Place of Issue:</b>	Warwick, Rhode Island
<b>Date of Issue:</b>	19-Jan-2023
<b>Signature:</b>	<div><div>DocuSigned by:</div><div><i>Daniel Campion</i></div><div> Signer Name: Daniel Campion Signing Reason: I approve this document Signing Time: 19-Jan-2023   7:23:42 AM PST 475F68F270444D42895AE26E3FC4EE5C</div></div>

**DECLARATION OF CONFORMITY Revision History:**

Version:	Detailed Change Description:
0	Initial Release of EU MDR Declaration of Conformity
1	Administrative update to align with updated DoC template (CBI-058 FRM20 Rev. 05) to include on behalf of on signatory section. Added Intended user from above to Intended Purpose section to align with template.