



EU DECLARATION OF CONFORMITY (DoC)

Manufacturer:	Davol Inc., a subsidiary of C. R. Bard, Inc. 100 Crossings Blvd Warwick, R.I. 02886 USA
Manufacturer SRN:	US-MF-000017971
Authorised Representative:	Becton Dickinson Ireland Limited Donore Road, Drogheda A92 YW26 Co. Louth, Ireland
Authorised Representative SRN:	IE-AR-000007610
Product:	<p>Trade Name: SorbaFix™ Absorbable Fixation System</p> <p>Intended Use: The SorbaFix™ Absorbable Fixation System is indicated for the approximation of soft tissue and fixation of surgical mesh to tissues during laparoscopic surgical procedures, such as hernia repair.</p> <p>Intended User: The SorbaFix™ device is intended to be used by surgical professionals who perform laparoscopic surgical procedures, such as hernia repair, on adult patients.</p> <p>Device Description: The SorbaFix™ Absorbable Fixation System is a sterile single-use device that delivers either 15 or 30 synthetic absorbable fasteners. The shaft of the SorbaFix™ Absorbable Fixation System is 36 cm in length, including a piloting tip. The fasteners are 6.7 mm in length and are manufactured from Poly (D, L)-lactide (100%). A single fastener contains D & C Violet N.2 colorant (< 0.20%). The fixation instrument shafts have an outer diameter of 5 mm and can be used with most 5 mm trocars in laparoscopic procedures. The device includes a fastener gauge located on the back of the handpiece. The gauge will move right to left as the fasteners are deployed and indicates the approximate level of fasteners remaining in the device. The clinical benefit of the SorbaFix™ Absorbable Fixation System is to provide strong and reliable fixation of surgical mesh to tissues and approximation of soft tissue during laparoscopic hernia repair procedures.</p>
Basic UDI-DI:	0801741QANBYMHX3

Risk Class and Rule:	Annex VIII, Rule 8 of MDR 2017/745 Class III
Intended Purpose:	<p>Indications for Use: The SorbaFix™ Absorbable Fixation System is indicated for the approximation of soft tissue and fixation of surgical mesh to tissues during laparoscopic surgical procedures, such as hernia repair.</p> <p>Intended User: The SorbaFix™ device is intended to be used by surgical professionals who perform laparoscopic surgical procedures, such as hernia repair, on adult patients.</p>
Notified Body:	<p>BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam Country: Netherlands 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"> Regulation (EU) 2017/745 of the European Parliament and of the Council on Medical Devices / REACH Regulation 	

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	EC CERTIFICATE No.: 731908 Certificate Expiration Date: 08 Sep 2026
<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	Not Applicable for Annex II & Technical Documentation Self Certified Devices.

Common Specifications (CS):

Common specifications have not been issued for this product.




Number	Title	Full or Partial Application
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
0113115	SorbaFix™ Absorbable Fixation System: 15 Absorbable Fasteners	Class III
0113116	SorbaFix™ Absorbable Fixation System: 30 Absorbable Fasteners	Class III

Authorised Signatory:	
Name & Title:	Daniel Campion Vice President Regulatory Affairs
On behalf of:	Davol Inc., a subsidiary of C. R. Bard, Inc., and now a subsidiary of Becton, Dickinson and Company 100 Crossings Blvd Warwick, RI 02886 USA
Place of Issue:	Warwick, Rhode Island
Date of Issue:	19-Jan-2023
Signature:	<div><div>DocuSigned by: <i>Daniel Campion</i></div><div> Signer Name: Daniel Campion Signing Reason: I approve this document Signing Time: 19-Jan-2023 7:31:01 AM PST 475F68F270444D42895AE26E3FC4EE5C</div></div>

DECLARATION OF CONFORMITY Revision History:

Version	Detailed Change Description
0	Originate and release Declaration of Conformity for EU MDR implementation
1	Update to Manufacturer SRN, Authorized Representative SRN, and Risk Class and Rule Section to add in Rule
2	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. Added SRN numbers for Manufacturer and Authorized Representative.