

EU Technical Documentation Assessment Certificate

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

MDR 731908 R000

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

Address:

100 Crossings Boulevard
Warwick
Rhode Island
02886
USA

Single Registration Number: Not Available

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):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2021-09-09**

Date: **2021-09-09**

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

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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:

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.

Risk Classification: Class III Implantable

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

Basic UDI-DI: 0801741QANBYMHX3

Device Name	Model
SorbaFix™ Absorbable Fixation System: 15 Absorbable Fasteners	0113115
SorbaFix™ Absorbable Fixation System: 30 Absorbable Fasteners	0113116

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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	3253186	Issued



First Issued: **2021-09-09**

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