By Royal Charter

EU Quality Management System Certificate

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

MDR 753283 R000

Manufacturer: Ethicon SARL

Address:
Puits Godet 20
Neuchatel
CH-2000
Switzerland

Single Registration Number: CH-MF-000013115

EU Authorised Representative: Johnson & Johnson Medical GmbH

Address:
Robert-Koch-Strasse 1
Norderstedt
22851
Germany

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 and Class IIb implantable devices an 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 Medical Devices

First Issue Date: **2023-02-10**

Current Issue Date: **2023-02-10**

Starting Validity Date: **2023-02-10**

Expiry Date: **2028-02-09**

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Device Schedule: Class III and Class IIb devices

Class III, Implantable	Intended purpose
SURGICEL™ Original and SURGICEL™ Nu-Knit Absorbable Haemostat	See MDR 753284
GYNECARE INTERCEED™ Absorbable Adhesion Barrier	See MDR 753285

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

Device(s)	Risk Classification
Retracting Devices	Class Ir
For Class Ir devices (Class I re-usable surgical instruments), the Notified Body conformity assessment is limited to the aspects relating to the reuse of the device.	

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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	3483882	Issued

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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.

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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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