English

ETHICON sarl
a Johnson & Johnson company

EU DECLARATION OF CONFORMITY

Manufacturer's Name	ETHICON SARL
Manufacturer's Address	Rue du Puits-Godet 20 CH-2000 Neuchâtel Switzerland
Manufacturer's Single Registration Number (SRN)	CH-MF-000013115
Authorized Representative's Name and Address	Johnson & Johnson Medical GmbH Robert-Koch-Strasse 1 22851 Norderstedt Germany
Authorized Representative's Single Registration Number (SRN)	DE-AR-000007712
Notified Body Name	BSI Group The Netherlands B.V.
Notified Body Identification Number	2797
Technical Documentation Number	100696190
Product and Trade Name(s)	SURGICEL™ Original Absorbable Haemostat SURGICEL™ NU-KNIT Absorbable Haemostat
Product Code(s)/Product Range and Description	Refer to Attachment 1
Intended Purpose	SURGICEL ™ Haemostat is used adjunctively in surgical procedures to assist in the control of capillary, venous, and small arterial haemorrhage when ligation or other conventional methods of control are impractical or ineffective.
Classification	Class III (Annex VIII, Rule 8)
GMDN Code	38771 – Plant Polysaccharide Haemostatic Agent, Bioabsorbable
EMDN Code	M040501
Basic UDI-DI value	See table below
Common Specifications	Common Specifications have not been issued.

Basic UDI-DI Device Name	Basic UDI-DI Device Model	Basic UDI-DI
Surgicel Original Absorbable Haemostat	Surgicel Original	0705031a008545G
Surgicel NU-KNIT Absorbable Haemostat	Surgicel NU-KNIT	

English

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EU DECLARATION OF CONFORMITY

This EU Declaration of Conformity is issued under the sole responsibility of the Manufacturer.

We, Ethicon, SARL, hereby declare the above listed Medical Device(s) complies with Medical Device Regulation (EU) 2017/745.

This declaration is made on the basis of:
EU Technical Documentation Assessment Certificate Number MDR 753284, issued by the Notified Body stated above, in accordance with Annex IX, Chapter II of the Medical Device Regulation (EU) 2017/7 45.

EU Quality System Certificate Number MDR 753283, issued by the Notified Body stated above, in accordance with Annex IX, Chapters I and III of Medical Device Regulation (EU) 2017/745.

SIGNATURE SECTION

Place of Issue	**Refer to Manufacturer's Address above**		
Signature		**Date**	21-APR-2023
Name/Title	Joseph Chmielewski, Director Regulatory Affairs		
Signature		**Date**	21 - APR - 2023
Name/Title	Angela Deuse Siqueira de Carvalho, Site Quality Head Neuchatel **Manufacturer's Person Responsible for Regulatory Compliance**		

Note: The English DoC is considered the "EN Master DoC". The dated signature present in the "EN Master DoC" will represent the date of validity for any translated DoCs.

ATTACHMENT 1

ETHICON sarl
a Johnson & Johnson company

EU DECLARATION OF CONFORMITY

Manufacturer's Name	Ethicon, SARL
Technical Documentation Number	100696190
Product and Trade Names(s)	SURGICEL™ Original Absorbable Haemostat SURGICEL ™NU-KNIT Absorbable Haemostat
Intended Purpose	SURGICEL ™Haemostat is used adjunctively in surgical procedures to assist in the control of capillary, venous, and small arterial haemorrhage when ligation or other conventional methods of control are impractical or ineffective.

Product Code	Product Description
1901E	SURGICEL ORIGINAL 2INX14IN (5.1CMX35.6CM)
1901EE	SURGICEL ORIGINAL 2INX14IN (5.1CMX35.6CM)
1901F	SURGICEL ORIGINAL 2INX14IN (5.1CMX35.6CM)
1901G	SURGICEL ORIGINAL 2INX14IN (5.1CMX35.6CM)
1901GB	SURGICEL ORIGINAL 2INX14IN (5.1CMX35.6CM)
1901P	SURGICEL ORIGINAL 2INX14IN (5.1CMX35.6CM)
1901SK	SURGICEL ORIGINAL 2INX14IN (5.1CMX35.6CM)
1902B	SURGICEL ORIGINAL 4INX8IN (10.2CMX20.3CM)
1902E	SURGICEL ORIGINAL 4INX8IN (10.2CMX20.3CM)
1902EE	SURGICEL ORIGINAL 4INX8IN (10.2CMX20.3CM)
1902F	SURGICEL ORIGINAL 4INX8IN (10.2CMX20.3CM)
1902G	SURGICEL ORIGINAL 4INX8IN (10.2CMX20.3CM)
1902GB	SURGICEL ORIGINAL 4INX8IN (10.2CMX20.3CM)
1902P	SURGICEL ORIGINAL 4INX8IN (10.2CMX20.3CM)
1902SK	SURGICEL ORIGINAL 4INX8IN (10.2CMX20.3CM)
1903B	SURGICEL ORIGINAL 2INX3IN(5.1CMX7.6CM)
1903E	SURGICEL ORIGINAL 2INX3IN(5.1CMX7.6CM)
1903EE	SURGICEL ORIGINAL 2INX3IN(5.1CMX7.6CM)
1903F	SURGICEL ORIGINAL 2INX3IN(5.1CMX7.6CM)
1903G	SURGICEL ORIGINAL 2INX3IN(5.1CMX7.6CM)
1903GB	SURGICEL ORIGINAL 2INX3IN(5.1CMX7.6CM)
1903P	SURGICEL ORIGINAL 2INX3IN(5.1CMX7.6CM)
1903SK	SURGICEL ORIGINAL 2INX3IN(5.1CMX7.6CM)
1906B	SURGICEL ORIGINAL 0.5INX2IN(1.3CMX5.1CM)

1906E	SURGICEL ORIGINAL 0.5INX2IN(1.3CMX5.1CM)
1906EE	SURGICEL ORIGINAL 0.5INX2IN(1.3CMX5.1CM)
1906F	SURGICEL ORIGINAL 0.5INX2IN(1.3CMX5.1CM)
1906GB	SURGICEL ORIGINAL 0.5INX2IN(1.3CMX5.1CM)
1906P	SURGICEL ORIGINAL 0.5INX2IN(1.3CMX5.1CM)
1906SK	SURGICEL ORIGINAL 0.5INX2IN(1.3CMX5.1CM)
W1911	SURGICEL ORIGINAL 2INX14IN (5.1CMX35.6CM)
W1912	SURGICEL ORIGINAL 4INX8IN(10.2CMX20.3CM)
W1913T	SURGICEL ORIGINAL 2INX3IN(5.1CMX7.6CM)
W1915T	SURGICEL ORIGINAL 0.5INX2IN(1.3CMX5.1CM)
1940GB	SURGICEL NU-KNIT 1INX1IN(2.5CMX2.5CM)
1940M1	SURGICEL NU-KNIT 1INX1IN(2.5CMX2.5CM)
1940SK	SURGICEL NU-KNIT 1INX1IN(2.5CMX2.5CM)
1941SK	SURGICEL NU-KNIT 1INX3.5IN(2.5CMX8.9CM)
1942SK	SURGICEL NU-KNIT 2INX3IN(5CMX7.6CM)
1943GB	SURGICEL NU-KNIT 3INX4IN(7.6CMX10.2CM)
1943M1	SURGICEL NU-KNIT 3INX4IN(7.6CMX10.2CM)
1943SK	SURGICEL NU-KNIT 3INX4IN(7.6CMX10.2CM)
1946M	SURGICEL NU-KNIT 6INX9IN(15.2CMX22.9CM)

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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EU Quality Management System Certificate

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

MDR 753283 R000

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.	

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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EU Quality Management System Certificate

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

MDR 753283 R000

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

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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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.
A Member of the BSI Group of Companies.

EU Technical Documentation Assessment Certificate

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

MDR 753284 R000

Manufacturer: Ethicon SARL

Address:
Puits Godet 20
Neuchatel
CH-2000
Switzerland

Single Registration Number: CH-MF-000013115

EU Authorised Representative: Johnson and Johnson Medical GmbH

Address:
Robert-Koch-Strasse 1
Norderstedt
22851
Germany

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 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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EU Technical Documentation Assessment Certificate

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

MDR 753284 R000

Intended Purpose as per the Instructions for Use:

SURGICEL™ Haemostat is used adjunctively in surgical procedures to assist in the control of capillary, venous, and small arterial haemorrhage when ligation or other conventional methods of control are impractical or ineffective.

Device Name	**Model**	**Type** (Codes as per (EU) 2017/2185)	**Risk Classification**	**Basic UDI-DI**
SURGICEL Original Absorbable Haemostat	SURGICEL Original	MDN 1104	Class III, Implantable	0705031a008545G
SURGICEL Nu-Knit Absorbable Haemostat	SURGICEL Nu-Knit	MDN 1104	Class III, Implantable	0705031a008545G

Additional Information:

Product Name (as Indicated on DoC)	**Product Code**	**Product Description**
SURGICEL™ Original Absorbable Haemostat	1901B	SURGICEL ORIGINAL 2INX14IN (5.1CMX35.6CM)
SURGICEL™ Original Absorbable Haemostat	1901E	SURGICEL ORIGINAL 2INX14IN (5.1CMX35.6CM)
SURGICEL™ Original Absorbable Haemostat	1901EE	SURGICEL ORIGINAL 2INX14IN (5.1CMX35.6CM)
SURGICEL™ Original Absorbable Haemostat	1901F	SURGICEL ORIGINAL 2INX14IN (5.1CMX35.6CM)
SURGICEL™ Original Absorbable Haemostat	1901G	SURGICEL ORIGINAL 2INX14IN (5.1CMX35.6CM)

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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EU Technical Documentation Assessment Certificate

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

MDR 753284 R000

SURGICEL™ Original Absorbable Haemostat	1901GB	SURGICEL ORIGINAL 2INX14IN (5.1CMX35.6CM)
SURGICEL™ Original Absorbable Haemostat	1901P	SURGICEL ORIGINAL 2INX14IN (5.1CMX35.6CM)
SURGICEL™ Original Absorbable Haemostat	1901SK	SURGICEL ORIGINAL 2INX14IN (5.1CMX35.6CM)
SURGICEL™ Original Absorbable Haemostat	1902B	SURGICEL ORIGINAL 4INX8IN (10.2CMX20.3CM)
SURGICEL™ Original Absorbable Haemostat	1902E	SURGICEL ORIGINAL 4INX8IN (10.2CMX20.3CM)
SURGICEL™ Original Absorbable Haemostat	1902EE	SURGICEL ORIGINAL 4INX8IN (10.2CMX20.3CM)
SURGICEL™ Original Absorbable Haemostat	1902F	SURGICEL ORIGINAL 4INX8IN (10.2CMX20.3CM)
SURGICEL™ Original Absorbable Haemostat	1902G	SURGICEL ORIGINAL 4INX8IN (10.2CMX20.3CM)
SURGICEL™ Original Absorbable Haemostat	1902GB	SURGICEL ORIGINAL 4INX8IN (10.2CMX20.3CM)
SURGICEL™ Original Absorbable Haemostat	1902P	SURGICEL ORIGINAL 4INX8IN (10.2CMX20.3CM)
SURGICEL™ Original Absorbable Haemostat	1902SK	SURGICEL ORIGINAL 4INX8IN (10.2CMX20.3CM)
SURGICEL™ Original Absorbable Haemostat	1903B	SURGICEL ORIGINAL 2INX3IN (5.1CMX7.6CM)
SURGICEL™ Original Absorbable Haemostat	1903E	SURGICEL ORIGINAL 2INX3IN (5.1CMX7.6CM)

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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EU Technical Documentation Assessment Certificate

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

MDR 753284 R000

SURGICEL™ Original Absorbable Haemostat	1903EE	SURGICEL ORIGINAL 2INX3IN (5.1CMX7.6CM)
SURGICEL™ Original Absorbable Haemostat	1903F	SURGICEL ORIGINAL 2INX3IN (5.1CMX7.6CM)
SURGICEL™ Original Absorbable Haemostat	1903G	SURGICEL ORIGINAL 2INX3IN (5.1CMX7.6CM)
SURGICEL™ Original Absorbable Haemostat	1903GB	SURGICEL ORIGINAL 2INX3IN (5.1CMX7.6CM)
SURGICEL™ Original Absorbable Haemostat	1903P	SURGICEL ORIGINAL 2INX3IN (5.1CMX7.6CM)
SURGICEL™ Original Absorbable Haemostat	1903SK	SURGICEL ORIGINAL 2INX3IN (5.1CMX7.6CM)
SURGICEL™ Original Absorbable Haemostat	1906B	SURGICEL ORIGINAL 0.5INX2IN (1.3CMX5.1CM)
SURGICEL™ Original Absorbable Haemostat	1906E	SURGICEL ORIGINAL 0.5INX2IN (1.3CMX5.1CM)
SURGICEL™ Original Absorbable Haemostat	1906EE	SURGICEL ORIGINAL 0.5INX2IN (1.3CMX5.1CM)
SURGICEL™ Original Absorbable Haemostat	1906F	SURGICEL ORIGINAL 0.5INX2IN (1.3CMX5.1CM)
SURGICEL™ Original Absorbable Haemostat	1906GB	SURGICEL ORIGINAL 0.5INX2IN (1.3CMX5.1CM)
SURGICEL™ Original Absorbable Haemostat	1906P	SURGICEL ORIGINAL 0.5INX2IN (1.3CMX5.1CM)
SURGICEL™ Original Absorbable Haemostat	1906SK	SURGICEL ORIGINAL 0.5INX2IN (1.3CMX5.1CM)

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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EU Technical Documentation Assessment Certificate

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

MDR 753284 R000

SURGICEL™ Original Absorbable Haemostat	W1911	SURGICEL ORIGINAL 2INX14IN (5.1CMX35.6CM)
SURGICEL™ Original Absorbable Haemostat	W1912	SURGICEL ORIGINAL 4INX8IN (10.2CMX20.3CM)
SURGICEL™ Nu-Knit Absorbable Haemostat	1940GB	SURGICEL NU-KNIT 1INX1IN (2.5CMX2.5CM)
SURGICEL™ Nu-Knit Absorbable Haemostat	1940M1	SURGICEL NU-KNIT 1INX1IN (2.5CMX2.5CM)
SURGICEL™ Nu-Knit Absorbable Haemostat	1940SK	SURGICEL NU-KNIT 1INX1IN (2.5CMX2.5CM)
SURGICEL™ Nu-Knit Absorbable Haemostat	1941SK	SURGICEL NU-KNIT 1INX3.5IN (2.5CMX8.9CM)
SURGICEL™ Nu-Knit Absorbable Haemostat	1942SK	SURGICEL NU-KNIT 2INX3IN (5CMX7.6CM)
SURGICEL™ Nu-Knit Absorbable Haemostat	1943GB	SURGICEL NU-KNIT 3INX4IN (7.6CMX10.2CM)
SURGICEL™ Nu-Knit Absorbable Haemostat	1943M1	SURGICEL NU-KNIT 3INX4IN (7.6CMX10.2CM)
SURGICEL™ Nu-Knit Absorbable Haemostat	1943SK	SURGICEL NU-KNIT 3INX4IN (7.6CMX10.2CM)
SURGICEL™ Nu-Knit Absorbable Haemostat	1946M	SURGICEL NU-KNIT 6INX9IN (15.2CMX22.9CM)

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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EU Technical Documentation Assessment Certificate

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

MDR 753284 R000

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	3581881	Issued

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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By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Ethicon, Inc.
1000 route 202
Raritan
New Jersey
08869
USA

Holds Certificate Number: FM 732364

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

Please see scope page.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2020-07-10
Effective Date: 2023-07-10
Latest Revision Date: 2023-07-07
Expiry Date: 2026-07-09

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Certificate No: FM 732364

Registered Scope:

Design and development, manufacture, packaging and distribution of sutures and ligatures (needled and non-needled, absorbable and non-absorbable, synthetic including stainless steel and non-synthetic, medicated and non-medicated), and suture cartridges (sterile), Surgical meshes (absorbable and non-absorbable, sterile), surgical mesh system (non-absorbable, sterile), Hemostasis devices (absorbable and non-absorbable, sterile), absorbable adhesion prevention devices composed of Oxidized Regenerated Cellulose ORC (sterile), tissue sealants and adhesives for internal and topical surgical applications (sterile), wound dressings (anti-microbial, sterile), surgical support tapes (absorbable & non-absorbable, sterile), umbilical cord tapes (sterile), Pelvic organ prolapse urogynaecological surgical mesh (sterile), cutaneous suturing needle (sterile, non-sterile), hysteroscopic systems including bipolar electrosurgical instruments and associated electrodes (sterile and non-sterile) and urinary stress incontinence devices (sterile and non-sterile), Surgical implant systems and devices, and tissue fixation devices (absorbable and non-absorbable, sterile) and accessories, Endoscopic and open instruments (sterile and non-sterile) and accessories, elastic tubing to secure veins, arteries, nerves and ureters (sterile), and fixation clips (sterile), Wound closure strips (sterile), Wound closure devices (sterile) and accessories. Other products including; closed wound drainage systems (sterile), delivery cannulas (sterile), temporary cardiac pacing wires (sterile), retention suture bridges (sterile), pledgets (sterile), surgical implants (sterile), surgical bone wax (sterile), electrosurgical Instruments and accessories (non-sterile), Design, development, production and distribution of Body Contouring Implants, Implantable Tissue Expanders, Accessories, and Sizers. Design, Development, Production, Servicing, and Distribution of Medical Devices for General Aspiration and Infiltration for Liposuction & Body Contouring. Sterilization services for other J&J company products. Distribution, packaging and labeling of devices on behalf of other J&J companies.

Original Registration Date: 2020-07-10
Effective Date: 2023-07-10
Latest Revision Date: 2023-07-07
Expiry Date: 2026-07-09

Certificate No: FM 732364

Location	Registered Activities
Ethicon, Inc. 655 Ethicon Circle Cornelia Georgia 30531 USA	The manufacture and distribution of raw materials for suture and specialty products from natural fibers, polymers, wire, stock, tissue sealants and adhesives for internal and typical surgical applications. Processes include polymer manufacture, extrusion, braiding, injection molding, needle forming, surface treatments, and the manufacture and packaging of surgical meshes (absorbable and non-absorbable).
Ethicon, LLC Highway 183 Km 8.3 San Lorenzo 00754 Puerto Rico	The manufacture, packaging and distribution of sutures and ligatures (needled and non-needled, absorbable and non-absorbable, synthetic including stainless steel and non-synthetic, non-medicated) and associated accessories (sterile), surgical support tapes (Non-absorbable) (sterile), temporary cardiac pacing wires (sterile), surgical mesh (non-absorbable) (sterile), pelvic organ prolapse urogynaecological surgical mesh (sterile), hemostasis devices (absorbable & non-absorbable) (sterile), absorbable adhesion prevention devices composed of Oxidized Regenerated Cellulose (ORC) (sterile), pledgets (sterile), polypropylene buttons (sterile), surgical bone wax (sterile), and tissue sealants and adhesives for internal and topical surgical applications (sterile) and endoscopic instruments (sterile) and Sterilization by dry heat of in-house products.
Ethicon, Inc. 3348 Pulliam Street San Angelo Texas 76905 USA	The manufacture, distribution and assembly of sutures and ligatures (needled and non-needled, absorbable, synthetic, medicated and non-medicated) and associated accessories (sterile), surgical meshes (absorbable) (sterile), wound closure devices (sterile) and tissue fixation devices (absorbable) and accessories (sterile). Sterilization of in-house products and other J&J company products.
Ethicon SARL Puits Godet 20 Neuchatel 2000 Switzerland	The Design and development, manufacture, packaging, storage and distribution of Absorbable adhesion prevention devices composed of Oxidized Regenerated Cellulose (ORC) (Sterile), Haemostasis Devices (Absorbable, Sterile), and Urinary Stress Incontinence Devices and accessories (Sterile & Non-Sterile).
Ethicon SARL Les Perveuils 10 Marin Epagnier CH-2074 Switzerland	The storage and distribution of absorbable adhesion prevention devices composed of Oxidized Regenerated Cellulose (ORC) (sterile), hemostasis Devices (absorbable, sterile), and urinary stress incontinence devices and accessories (sterile & non-sterile).

Original Registration Date: 2020-07-10

Effective Date: 2023-07-10

Latest Revision Date: 2023-07-07

Expiry Date: 2026-07-09

Certificate No: FM 732364

Location	Registered Activities
Ethicon, LLC 475 C Street Los Frailes Industrial Park Suite 401 Guaynabo 00969 Puerto Rico	The manufacture and distribution of sutures and ligatures (needled and non-needled, absorbable and non-absorbable, synthetic including stainless steel and non-synthetic, medicated and non-medicated) and associated accessories (sterile), suture cartridges (sterile), pledgets (sterile), umbilical cord tape (sterile), retention suture bridge (sterile), surgical support tapes (non-absorbable)(sterile), temporary cardiac pacing wires (sterile), tissue fixation devices (absorbable, sterile) and wound closure devices(strile), elastic tubing to secure veins, arteries, nerves and ureters (sterile), fixation clips (sterile), and endoscopic instruments and accessories (non-sterile), surgical bone wax (sterile).
Ethicon, Inc 1420 Olympic Drive Athens Georgia 30601 USA	The manufacture of raw materials for suture from polymers. Processes include polymer manufacture and extrusion (absorbable and non-absorbable).

Original Registration Date: 2020-07-10

Effective Date: 2023-07-10

Latest Revision Date: 2023-07-07

Expiry Date: 2026-07-09

Certificate No: FM 732364

Location	Registered Activities
Ethicon, Inc. 1000 route 202 Raritan New Jersey 08869 USA	Design and development, Regulatory Compliance of sutures and ligatures (needled and non-needled, absorbable and non-absorbable, synthetic including stainless steel and non-synthetic, medicated and non-medicated) and suture cartridges (sterile), Surgical meshes (absorbable and nonabsorbable, sterile), surgical mesh system (non-absorbable, sterile), Hemostasis devices (absorbable and non-absorbable, sterile), absorbable adhesion prevention devices composed of Oxidized Regenerated Cellulose ORC (sterile), tissue sealants and adhesives for internal and topical surgical applications (sterile), wound dressings (anti-microbial, sterile), surgical support tapes (absorbable & non-absorbable, sterile), umbilical cord tapes (sterile), Pelvic organ prolapse urogynaecological surgical mesh (sterile), cutaneous suturing needle (sterile, non-sterile), hysteroscopic systems including bipolar electrosurgical instruments and associated electrodes (sterile and non-sterile) and urinary stress incontinence devices (sterile and non-sterile), Surgical implant systems and devices, and tissue fixation devices (absorbable and non-absorbable, sterile) and accessories, Endoscopic and open instruments (sterile and non-sterile) and accessories, elastic tubing to secure veins, arteries, nerves and ureters (sterile), and fixation clips (sterile), Wound closure strips (sterile), wound closure devices (sterile) and accessories, Other products including; closed wound drainage systems (sterile), delivery cannulas (sterile), temporary cardiac pacing wires (sterile), retention suture bridges (sterile), pledgets (sterile), surgical implants (sterile), surgical bone wax (sterile), electrosurgical Instruments and accessories (non-sterile). Design, development of Body Contouring Implants, Implantable Tissue Expanders, Accessories, and Sizers and Medical Devices for General Aspiration and Infiltration for Liposuction & Body Contouring, Distribution, packaging and labelling of devices on behalf of other J&J companies.
Johnson & Johnson Medical (China) Ltd. No.75 Nangu Zhi Road Minhang Shanghai China	Design and Development, Production and Distribution of Silk Braided Non-absorbable Suture.

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Effective Date: 2023-07-10

Latest Revision Date: 2023-07-07

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Location	Registered Activities
Ethicon, Inc. Calle Durango No. 2751 Lote Bravo Ciudad Juarez Chihuahua C.P. 32575 Mexico	Manufacture and assembly of sutures (needled and non-needled, absorbable and non-absorbable, synthetic including stainless steel and non-synthetic , medicated and non-medicated), and associated accessories (sterile), suture cartridges (sterile), Pledget (Sterile), umbilical cord tape (sterile), surgical support tapes (non-absorbable) (sterile), temporary cardiac pacing wires (sterile), wound closure devices (sterile), and tissue fixation devices (absorbable, sterile), elastic tubing to secure veins, arteries, nerves and ureters (sterile), fixation clips (sterile), and endoscopic instruments (non-sterile).
Johnson and Johnson Private Limited B 15/1, MIDC, Waluj Aurangabad Maharashtra 431 136 India	The design, development, manufacture & Distribution of Surgical Sutures, Polypropylene Meshes, Polypropylene Hernia system, Kits, tapes (Nylon, Polyester) and Sterilization by ethylene oxide of in-house products.
Johnson & Johnson International c/o European Logistics Centre Leonardo Da Vincilaan 15 BE-1831 Diegem Belgium	The design, development, manufacture and distribution of pledgets (sterile), surgical meshes (partially absorbable, absorbable, and non-absorbable) (sterile), surgical mesh systems (non-absorbable)(sterile), sutures and ligatures (needled and non-needled, absorbable and nonabsorbable, synthetic and non-synthetic, medicated and non-medicated), and associated accessories (sterile and non-sterile), and endoscopic instruments (non-sterile), wound closure devices (sterile), and accessories, surgical implants (sterile), surgical bone wax (sterile), and pelvic organ prolapse urogynaecological surgical mesh (sterile).
Johnson & Johnson MEDICAL GmbH Robert-Koch-Strasse 1 Norderstedt 22851 Germany	The design, development, manufacture and distribution of wound closure devices (sterile) and accessories, endoscopic and open instruments (non-sterile), electrosurgical instruments and accessories (non-sterile) and kits (sterile). Manufacture of suture and ligatures (needled and non-needled, absorbable and non-absorbable, synthetic, and non-synthetic, medicated and non-medicated) (sterile), surgical meshes (partially absorbable, absorbable and non-absorbable) (sterile), surgical mesh systems (non-absorbable) (sterile), pledgets (sterile), endoscopic and open instruments (non-sterile) and accessories, wound closures devices (sterile) and accessories, surgical implants (sterile), and pelvic organ prolapse urogynaecological surgical mesh (sterile), and synthetic absorbable sterile surgical implants to support the staple line, cutaneous suturing, needle (non-sterile). Sterilization by ethylene oxide and gamma irradiation of in-house products and other J&J company products.

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Expiry Date: 2026-07-09

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Location	Registered Activities
Johnson & Johnson MEDICAL GmbH Oststrasse 1 Norderstedt 22844 Germany	Repackaging and relabeling of finished products.
Johnson & Johnson do Brasil Indústria e Comércio de Produtos para Saúde Ltda. Rod. Presidente Dutra - KM 154 São José dos Campos São Paulo 12240-908 Brasil	Manufacture of suture and ligatures (needled and non-needled, absorbable and non-absorbable, synthetic and non-synthetic, including those made of stainless steel and from animal tissue, medicated and non-medicated, sterile), surgical bone wax (sterile), surgical meshes (absorbable and non-absorbable) (sterile). Sterilization by ethylene oxide and gamma irradiation of in-house products and other J&J company products.
Mentor 3041 Skyway Circle North Irving Texas 75038 USA	Design, Development, Production, Servicing and Distribution of Body Contouring Implants, Sizers, and Medical Devices for General Aspiration, and Infiltration for Liposuction and Body Contouring.
Mentor 555 Airline Drive Coppell Texas 75019 USA	Distribution and repackaging of Body Contouring Implants, Sizers, and Medical Devices for General Aspiration, and Infiltration for Liposuction, & Body Contouring. Distribution, packaging and labeling of devices on behalf of other J&J companies.

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