


English	
	
<b>EU DECLARATION OF CONFORMITY</b>	
<b>Manufacturer's Name</b>	ETHICON SARL
<b>Manufacturer's Address</b>	Puits Godet 20 Neuchâtel CH-2000 Switzerland
<b>Manufacturer's Single Registration Number (SRN)</b>	CH-MF-000013115
<b>Authorized Representative's Name and Address</b>	Johnson & Johnson Medical GmbH Robert-Koch-Strasse 1 22851 Norderstedt Germany
<b>Authorized Representative's Single Registration Number (SRN)</b>	DE-AR-000007712
<b>Notified Body Name</b>	BSI Group The Netherlands B.V.
<b>Notified Body Identification Number</b>	2797
<b>Technical Documentation Number</b>	100696190
<b>Product and Trade Name(s)</b>	SURGICEL™ Original Absorbable Haemostat SURGICEL™ NU-KNIT Absorbable Haemostat
<b>Product Code(s)/Product Range and Description</b>	Refer to Attachment 1
<b>Intended Purpose</b>	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.
<b>Classification</b>	Class III (Annex VIII, Rule 8)
<b>GMDN Code</b>	38771 – Plant Polysaccharide Haemostatic Agent, Bioabsorbable
<b>EMDN Code</b>	M040501
<b>Basic UDI-DI Device Name</b>	Surgicel Original Absorbable Haemostat Surgicel NU-KNIT Absorbable Haemostat
<b>Basic UDI-DI Device Model</b>	Surgicel Original, Surgicel NU-KNIT
<b>Basic UDI-DI value</b>	0705031a008545G
<b>Common Specifications</b>	Common Specifications have not been issued for the product in scope.
<b>This EU Declaration of Conformity is issued under the sole responsibility of the Manufacturer.</b>	

English

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**EU DECLARATION OF CONFORMITY**

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) 2017/745.

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**

<b>Place of Issue</b>	Refer to Manufacturer's Address above		
<b>Signature</b>	Electronically signed by: Tobias Davis Reason: I am approving this document Date: Jan 7, 2025 10:50 GMT <i>Tobias Davis</i>	<b>Date</b>	Refer to date from electronic signature
<b>Name/Title</b>	Tobias Davis, Director Regulatory Affairs		
<b>Signature</b>	Electronically signed by: Anthony Bataillard Reason: I am approving this document Date: Jan 6, 2025 09:56 GMT+1 <i>Anthony Bataillard</i>	<b>Date</b>	Refer to date from electronic signature
<b>Name/Title</b>	Anthony Bataillard, Quality Operations Manager		
	<b>Manufacturer's Person Responsible for Regulatory Compliance</b>		

**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**

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**EU DECLARATION OF CONFORMITY**

<b>Manufacturer's Name</b>	Ethicon, SARL
<b>Technical Documentation Number</b>	100696190
<b>Product and Trade Names(s)</b>	SURGICEL™ Original Absorbable Haemostat, SURGICEL™ NU-KNIT Absorbable Haemostat
<b>Intended Purpose</b>	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.

<b>Product Code</b>	<b>Product Description</b>
1901B	SURGICEL ORIGINAL 2INX14IN (5.1CMX35.6CM)
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)
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)










# 100892071 DoC for SURGICEL Fabric Ethicon SARL English

Final Audit Report

2025-01-07

Created:	2025-01-03
By:	Kristin Machado (KDiStef1@ITS.JNJ.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAA8tZqZxgU5MnAcp9jHbcRxh_H58l4_ybE

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