

<h1 style="margin: 0;">ETHICON^{LLC}</h1> <p style="margin: 0;">a <i>Johnson & Johnson</i> company</p>									
EU DECLARATION OF CONFORMITY									
Manufacturer's Name	ETHICON, LLC								
Manufacturer's Address	Highway 183 Km 8.3 San Lorenzo, Puerto Rico 00754 USA								
Manufacturer's Single Registration Number (SRN)	US-MF-000013112								
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	100696211								
Product Name	MERSILENE™ Polyester Sterile Synthetic Non-Absorbable Surgical Suture								
Product Code(s)/Product Range and Description	Refer to Attachment 1 Refer to Attachment 2								
Intended Purpose	MERSILENE™ Suture is indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurosurgical procedures.								
Classification	Class III (Annex VIII, Rule 8)								
GMDN Code	GMDN 13906, Polyester suture, non-bioabsorbable, multifilament								
EMDN Code	H0102010102 Non-absorbable synthetic sutures, polyester and derivatives monofilament H0102010202 Non-absorbable synthetic sutures, polyester multifilament								
Basic UDI-DI	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 33%;">Basic UDI-DI Device Name</th> <th style="width: 33%;">Basic UDI-DI Device Model</th> <th style="width: 33%;">Basic UDI-DI</th> </tr> </thead> <tbody> <tr> <td>MERSILENE Suture</td> <td>MERSILENE</td> <td>0705031a014495A</td> </tr> </tbody> </table>			Basic UDI-DI Device Name	Basic UDI-DI Device Model	Basic UDI-DI	MERSILENE Suture	MERSILENE	0705031a014495A
Basic UDI-DI Device Name	Basic UDI-DI Device Model	Basic UDI-DI							
MERSILENE Suture	MERSILENE	0705031a014495A							
Common Specifications	Common Specifications have not been issued.								

ETHICON LLC

a *Johnson & Johnson* company

EU DECLARATION OF CONFORMITY

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

We, Ethicon, LLC., 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 753185, 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 753178, 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

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

Place of Issue	Refer to Manufacturer's Address above		
Signature		Date	27-MAR-2023
Name/Title	Valerie Smith-Beyer, Director Regulatory Affairs		
Signature		Date	27/march/2023
Name/Title	Jennifer Ruiz, Site Quality Lead		
	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 ^{LLC}	
a <i>Johnson & Johnson</i> company	
EU DECLARATION OF CONFORMITY	
Technical Documentation Number	100696211
Manufacturer's Name	Ethicon LLC, San Lorenzo

Suture Characteristics	Range
Suture Material (Absorbable/Non-Absorbable)	Non-Absorbable
Suture Gauge Size	0.1 – 6.0 (Metric)
Suture Length	10 cm – 150 cm
Suture Dyed/Undyed	Dyed / Undyed
Suture Color (If dyed)	Green
Coated/Uncoated	Uncoated
Multifilament/Monofilament	Multifilament / Monofilament
Accessories to suture type	N/A
Needed/Non-Needed	Needled (also available with CONTROL RELEASE™ needles) /Non-Needed
Number of Needles per Suture	Single Armed / Double Armed
Needle Material	420 SS, 455 SS, 4310 SS, and ETHALLOY
Needle Coating	Silicone, MULTIPASS, CERBERUS
Needle Shape	Straight / Curve
Needle Color	Silver / Black
Needle Length	2 mm – 90 mm
Needle Wire Diameter	0.03 mm – 1.80 mm

ATTACHMENT 2

<h1>ETHICON LLC</h1> <p>a <i>Johnson & Johnson</i> company</p>	
EU DECLARATION OF CONFORMITY	
Manufacturer's Name	Ethicon LLC, San Lorenzo
Technical Documentation Number	100696211
Product and Trade Names(s)	MERSILENE™ Polyester Sterile Synthetic Non-Absorbable Surgical Suture
Intended Purpose	MERSILENE™ Suture is indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurosurgical procedures.

LIST OF PRODUCT CODES		
Product Code	Product Description	EMDN Code
1617H	MERSILENE GRN 18IN(45CM) USP4-0(M1.5) S/A PS-2 PRM	H0102010202
1624H	MERSILENE GRN 30IN(75CM) USP2-0(M3) S/A FSLX	H0102010202
18513G	MERSILENE GRN 18IN(45CM) USP4-0(M1.5) S/A V-5	H0102010202
EH7164H	MERSILENE GRN 18IN(45CM) USP4-0(M1.5) S/A PS-2 PRM MP	H0102010202
EH7325H	MERSILENE GRN 30IN(75CM) USP0(M3.5) S/A CP-2	H0102010202
EH7350H	MERSILENE GRN 30IN(75CM) USP1(M4) S/A CP-1	H0102010202
EH7387H	MERSILENE GRN 30IN(75CM) USP2-0(M3) S/A SH-1	H0102010202
EH7554H	MERSILENE GRN 30IN(75CM) USP2-0(M3) S/A PS-1 PRM MP	H0102010202
EH7559H	MERSILENE GRN 18IN(45CM) USP2-0(M3) S/A PS-2 PRM MP	H0102010202
EH7637H	MERSILENE GRN 30IN(75CM) USP0(M3.5) S/A FSL	H0102010202
EH7638H	MERSILENE GRN 30IN(75CM) USP2-0(M3) S/A FSL	H0102010202
EH7689H	MERSILENE GRN 18IN(45CM) USP3-0(M2) S/A X-1	H0102010202
EH7750H	MERSILENE GRN 18IN(45CM) USP3-0(M2) S/A PS-2 PRM MP	H0102010202
F1533H	MERSILENE GRN 30IN(75CM) USP0(M3.5) S/A MH-1	H0102010202
F2502	MERSILENE GRN 30IN(75CM) USP3-0(M2) S/A FS-2	H0102010202
F2503	MERSILENE GRN 30IN(75CM) USP2-0(M3) S/A FS-1	H0102010202
F2505	MERSILENE GRN 30IN(75CM) USP0(M3.5) S/A FS	H0102010202
F2505H	MERSILENE GRN 30IN(75CM) USP0(M3.5) S/A FS	H0102010202
F2506	MERSILENE GRN 30IN(75CM) USP1(M4) S/A FS	H0102010202
F2506H	MERSILENE GRN 30IN(75CM) USP1(M4) S/A FS	H0102010202
F2507	MERSILENE GRN 30IN(75CM) USP2-0(M3) S/A FSL	H0102010202
F2513	MERSILENE GRN 30IN(75CM) USP0(M3.5) S/A X-1	H0102010202
F2514H	MERSILENE GRN 30IN(75CM) USP2-0(M3) S/A CP-2	H0102010202
F2515	MERSILENE GRN 30IN(75CM) USP0(M3.5) S/A CP-2	H0102010202
F2516	MERSILENE GRN 30IN(75CM) USP1(M4) S/A CP-2	H0102010202
F2516H	MERSILENE GRN 30IN(75CM) USP1(M4) S/A CP-2	H0102010202
F2518H	MERSILENE GRN 30IN(75CM) USP2-0(M3) S/A CP-1	H0102010202
F2519H	MERSILENE GRN 30IN(75CM) USP0(M3.5) S/A CP-1	H0102010202

F2520H	MERSILENE GRN 30IN(75CM) USP1(M4) S/A CP-1	H0102010202
F2525	MERSILENE GRN 30IN(75CM) USP1(M4) S/A CP	H0102010202
F2542	MERSILENE GRN 30IN(75CM) USP2-0(M3) S/A CPA	H0102010202
F2542H	MERSILENE GRN 30IN(75CM) USP2-0(M3) S/A CPA	H0102010202
F2543	MERSILENE GRN 30IN(75CM) USP0(M3.5) S/A CPA	H0102010202
F2543H	MERSILENE GRN 30IN(75CM) USP0(M3.5) S/A CPA	H0102010202
F2544	MERSILENE GRN 30IN(75CM) USP1(M4) S/A CPA	H0102010202
F2544H	MERSILENE GRN 30IN(75CM) USP1(M4) S/A CPA	H0102010202
F2556	MERSILENE GRN 30IN(75CM) USP2-0(M3) S/A FS-2	H0102010202
F2557H	MERSILENE GRN 30IN(75CM) USP1(M4) S/A FSL	H0102010202
F2560	MERSILENE GRN 30IN(75CM) USP2-0(M3) S/A FSLX	H0102010202
F2561	MERSILENE GRN 30IN(75CM) USP0(M3.5) S/A FSLX	H0102010202
F2569	MERSILENE GRN 30IN(75CM) USP2-0(M3) S/A FS	H0102010202
F2569H	MERSILENE GRN 30IN(75CM) USP2-0(M3) S/A FS	H0102010202
FR831	MERSILENE GRN 30IN(75CM) USP3-0(M2) S/A SH PLUS	H0102010202
FR832	MERSILENE GRN 30IN(75CM) USP2-0(M3) S/A SH PLUS	H0102010202
FR833	MERSILENE GRN 30IN(75CM) USP0(M3.5) S/A SH PLUS	H0102010202
FR834	MERSILENE GRN 30IN(75CM) USP1(M4) S/A SH	H0102010202
FR842	MERSILENE GRN 30IN(75CM) USP2-0(M3) S/A MH	H0102010202
FR843	MERSILENE GRN 30IN(75CM) USP0(M3.5) S/A MH PLUS	H0102010202
FR844	MERSILENE GRN 30IN(75CM) USP1(M4) S/A MH PLUS	H0102010202
FR871	MERSILENE GRN 30IN(75CM) USP3-0(M2) S/A RB-1 PLUS	H0102010202
FR872	MERSILENE GRN 30IN(75CM) USP2-0(M3) S/A RB-1 PLUS	H0102010202
FR964H	MERSILENE GRN 30IN(75CM) USP0(M3.5) S/A V-7	H0102010202
P1625H	MERSILENE GRN 30IN(75CM) USP0(M3.5) S/A FSLX	H0102010202
P1626H	MERSILENE GRN 30IN(75CM) USP1(M4) S/A FSLX	H0102010202
R424H	MERSILENE GRN 30IN(75CM) USP0(M3.5) S/A CT-1	H0102010202
R665H	MERSILENE WHT 18IN(45CM) USP2-0(M3) S/A FS	H0102010202
R677H	MERSILENE WHT 18IN(45CM) USP2-0(M3) S/A FSL	H0102010202
R690G	MERSILENE WHT 18IN(45CM) USP5-0(M1) S/A P-3 PRM MP	H0102010202
R691G	MERSILENE WHT 18IN(45CM) USP4-0(M1.5) S/A P-3 PRM MP	H0102010202
R832H	MERSILENE GRN 30IN(75CM) USP3-0(M2) S/A SH	H0102010202
R833H	MERSILENE GRN 30IN(75CM) USP2-0(M3) S/A SH	H0102010202
R834H	MERSILENE GRN 30IN(75CM) USP0(M3.5) S/A SH	H0102010202
R843H	MERSILENE GRN 30IN(75CM) USP2-0(M3) S/A MH	H0102010202
R844H	MERSILENE GRN 30IN(75CM) USP0(M3.5) S/A MH	H0102010202
R845H	MERSILENE GRN 30IN(75CM) USP1(M4) S/A MH	H0102010202
R872H	MERSILENE GRN 30IN(75CM) USP3-0(M2) S/A RB-1	H0102010202
R873H	MERSILENE GRN 30IN(75CM) USP2-0(M3) S/A RB-1	H0102010202
R952H	MERSILENE GRN 30IN(75CM) USP4-0(M1.5) S/A V-5	H0102010202
R964H	MERSILENE GRN 30IN(75CM) USP2-0(M3) S/A V-7	H0102010202
R995G	MERSILENE GRN 30IN(75CM) USP1(M4) S/A CP	H0102010202
W291H	MERSILENE GRN 30IN(75CM) USP0(M3.5) S/A MH-1	H0102010202
W832	MERSILENE WHT 18IN(45CM) USP4-0(M1.5) D/A S-24	H0102010202
18506G	MERSILENE GRN 18IN(45CM) USP3-0(M2) S/A V-5	H0102010202

18516G	MERSILENE GRN 18IN(45CM) USP3-0(M2) S/A V-6	H0102010202
18521G	MERSILENE GRN 18IN(45CM) USP4-0(M1.5) S/A J-1	H0102010202
EH7147H	MERSILENE GRN 18IN(45CM) USP4-0(M1.5) S/A FS-2	H0102010202
EH7148H	MERSILENE WHT 18IN(45CM) USP4-0(M1.5) S/A FS-2	H0102010202
EH7352H	MERSILENE GRN 18IN(45CM) USP3-0(M2) S/A FS-2	H0102010202
EH7385H	MERSILENE GRN 30IN(75CM) USP4-0(M1.5) S/A SH-1 PLUS	H0102010202
EH7386H	MERSILENE GRN 30IN(75CM) USP3-0(M2) S/A SH-1 PLUS	H0102010202
EH7526H	MERSILENE GRN 30IN(75CM) USP1(M4) S/A SH	H0102010202
EH7546H	MERSILENE GRN 18IN(45CM) USP3-0(M2) S/A J-1	H0102010202
EH7683H	MERSILENE GRN 18IN(45CM) USP2-0(M3) S/A FS-1	H0102010202
EH7684H	MERSILENE GRN 18IN(45CM) USP3-0(M2) S/A FS-1	H0102010202
F1506	MERSILENE GRN 30IN(75CM) USP1(M4) S/A TE PLUS	H0102010202
F1532	MERSILENE GRN 30IN(75CM) USP2-0(M3) S/A MH-1 PLUS	H0102010202
F1533	MERSILENE GRN 30IN(75CM) USP0(M3.5) S/A MH-1	H0102010202
F1534	MERSILENE GRN 30IN(75CM) USP1(M4) S/A MH-1 PLUS	H0102010202
F2508	MERSILENE GRN 30IN(75CM) USP0(M3.5) S/A FSL	H0102010202
F2514	MERSILENE GRN 30IN(75CM) USP2-0(M3) S/A CP-2	H0102010202
F2518	MERSILENE GRN 30IN(75CM) USP2-0(M3) S/A CP-1	H0102010202
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F2557	MERSILENE GRN 30IN(75CM) USP1(M4) S/A FSL	H0102010202
F2562	MERSILENE GRN 30IN(75CM) USP1(M4) S/A FSLX	H0102010202
F2570	MERSILENE GRN 30IN(75CM) USP3-0(M2) S/A FSL	H0102010202
FR964	MERSILENE GRN 30IN(75CM) USP0(M3.5) S/A V-7	H0102010202
FR965	MERSILENE GRN 30IN(75CM) USP1(M4) S/A V-7	H0102010202
FR965H	MERSILENE GRN 30IN(75CM) USP1(M4) S/A V-7	H0102010202
P574H	MERSILENE GRN 30IN(75CM) USP0(M3.5) S/A MH	H0102010202
R633H	MERSILENE WHT 18IN(45CM) USP4-0(M1.5) S/A FS-2S	H0102010202
R647H	MERSILENE WHT 18IN(45CM) USP3-0(M2) S/A FS-1	H0102010202
R670H	MERSILENE GRN 18IN(45CM) USP5-0(M1) S/A FS-3	H0102010202
R675H	MERSILENE GRN 30IN(75CM) USP3-0(M2) S/A FSL	H0102010202
R683H	MERSILENE GRN 18IN(45CM) USP4-0(M1.5) S/A FS-2S	H0102010202
R691H	MERSILENE WHT 18IN(45CM) USP4-0(M1.5) S/A P-3 PRM	H0102010202
R698H	MERSILENE GRN 18IN(45CM) USP5-0(M1) S/A P-3 PRM	H0102010202
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R730H	MERSILENE GRN 18IN(45CM) USP5-0(M1) S/A J-1	H0102010202
R870H	MERSILENE GRN 30IN(75CM) USP5-0(M1) S/A RB-1 PLUS	H0102010202
R871H	MERSILENE GRN 30IN(75CM) USP4-0(M1.5) S/A RB-1 PLUS	H0102010202
R943H	MERSILENE GRN 30IN(75CM) USP3-0(M2) S/A V-4	H0102010202
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W1755	MERSILENE GRN 12IN(30CM) USP10-0(M0.2) D/A TG160-6	H0102010102
W1758	MERSILENE GRN 12IN(30CM) USP11-0(M0.1) D/A TG160-6	H0102010102
W1775	MERSILENE GRN 12IN(30CM) USP10-0(M0.2) D/A TG140-6	H0102010102
W1785	MERSILENE GRN 12IN(30CM) USP11-0(M0.1) D/A TG140-6	H0102010102
W290H	MERSILENE GRN 30IN(75CM) USP2-0(M3) S/A MH-1	H0102010202

