

English			
ETHICON_{LLC} a Johnson & Johnson company EU DECLARATION OF CONFORMITY			
Manufacturer's Name		Ethicon LLC	
Manufacturer's Address		475 C Street Los Frailes Industrial Park Suite 401 Guaynabo, Puerto Rico 00969 USA	
Manufacturer's Single Registration Number (SRN)		US-MF-000013111	
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		100885069	
Product and Trade Name(s)		ETHILON Polyamide 6 or 6,6 Sterile Synthetic Non-Absorbable Surgical Suture	
Product Code(s)/Product Range and Description		Refer to Attachment 1 for Product Range Refer to Attachment 2 for list of Product Codes and Description	
Intended Purpose		ETHILON 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		38000, Nylon suture, non-bioabsorbable, monofilament	
EMDN Code		H010201010101 Polyamide Monofilament with Needle H010201010102 Polyamide Monofilament without Needle	
Basic UDI-DI value		Basic UDI-DI Device Name	Basic UDI-DI Device Model
		Ethilon Polyamide 6 or 6,6, Sterile Synthetic Non-Absorbable Surgical Suture	ETHILON
		0705031a0120042	
Common Specifications		Common Specifications have not been issued	

English	
ETHICON LLC a <i>Johnson & Johnson</i> company EU DECLARATION OF CONFORMITY	
Common Specifications	Common Specifications have not been issued
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 719648, 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 719610, 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	14Jul2023
Name/Title	Valerie Smith-Beyer, Director Regulatory Affairs		
Signature		Date	14/JUL/23
Name/Title	Carmen Gracia, Supply Chain Quality Business 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
Suture Product Range

ETHICON^{LLC} a Johnson & Johnson company EU DECLARATION OF CONFORMITY	
Technical Documentation Number	100885069
Manufacturer's Name	Ethicon LLC, Guaynabo

Suture Characteristics	Range
Suture Material (Absorbable/Non-Absorbable)	Non-Absorbable
Suture Gauge Size	0.1 – 5.0 (Metric)
Suture Length	5 cm – 200 cm
Suture Dyed/Undyed	Dyed / Undyed
Suture Color (If dyed)	Black / Green
Coated/Uncoated	Uncoated
Multifilament/Monofilament	Monofilament
Accessories to suture type	Retention Tubing
Needled/Non-Needled	Non-Needled/Needled
Number of Needles per Suture	Single Armed / Double Armed
Needle material	420 SS, 4310 SS, 455 SS and ETHALLOY
Needle coating	Silicone, MULTIPASS and CERBERUS
Needle Shape	Straight / Curve
Needle Color	Black / Silver
Needle Length	3.5 mm - 90 mm
Needle Wire Diameter	0.051 mm – 1.270 mm

ATTACHMENT 2

Product Codes and Description

ETHICON LLC a <i>Johnson & Johnson</i> company EU DECLARATION OF CONFORMITY	
Manufacturer's Name	Ethicon LLC
Technical Documentation Number	100885069
Product and Trade Name(s)	ETHILON Polyamide 6 or 6,6 Sterile Synthetic Non-Absorbable Surgical Suture
Intended Purpose	ETHILON Suture is indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic, and neurosurgical procedures.

Product Code	Product Description	EMDN Code
1647H	ETHILON BLK 18IN(45CM) USP7-0(M0.5) S/A P-6 PRIME	H010201010101
1696G	ETHILON BLK 18IN(45CM) USP7-0(M0.5) S/A P-1 PRM MP	H010201010101
1696H	ETHILON BLK 18IN(45CM) USP7-0(M0.5) S/A P-1 PRIME	H010201010101
1716G	ETHILON BLK 12IN(30CM) USP8-0(M0.4) D/A TG175-8	H010201010101
1717G	ETHILON BLK 12IN(30CM) USP9-0(M0.3) D/A GS-9	H010201010101
1718G	ETHILON BLK 12IN(30CM) USP10-0(M0.2) D/A GS-9	H010201010101
18544G	ETHILON BLK 18IN(45CM) USP6-0(M0.7) S/A ACC-1 VB	H010201010101
2808G	ETHILON BLK 6IN(15CM) USP8-0(M0.4) S/A BV130-5 MP	H010201010101
2809G	ETHILON BLK 6IN(15CM) USP9-0(M0.3) S/A BV-2	H010201010101
2810G	ETHILON BLK 6IN(15CM) USP10-0(M0.2) S/A BV-2	H010201010101
2850G	ETHILON BLK 5IN(13CM) USP10-0(M0.2) S/A BV75-4	H010201010101

Product Code	Product Description	EMDN Code
2860G	ETHILON BLK 5IN(13CM) USP10-0(M0.2) S/A BVH100-3	H010201010101
2870G	ETHILON BLK 5IN(13CM) USP10-0(M0.2) S/A BV75-3	H010201010101
2871G	ETHILON BLK 5IN(13CM) USP11-0(M0.1) S/A BV75-3	H010201010101
2881G	ETHILON BLK 5IN(13CM) USP11-0(M0.1) S/A BV50-3	H010201010101
3460TG	ETHILON BLK 3X20IN(50CM) USP2(M5) S/A LR	H010201010101
660H	ETHILON BLK 18IN(45CM) USP6-0(M0.7) S/A FS-3	H010201010101
667H	ETHILON BLK 18IN(45CM) USP6-0(M0.7) S/A C-2	H010201010101
668H	ETHILON BLK 18IN(45CM) USP5-0(M1) S/A C-2	H010201010101
670E	ETHILON BLK 60IN(150CM) USP1(M4) S/A CTX	H010201010101
7000G	ETHILON BLK 12IN(30CM) USP10-0(M0.2) D/A CS160-6	H010201010101
7003G	ETHILON BLK 12IN(30CM) USP10-0(M0.2) D/A CS140-6	H010201010101
7008G	ETHILON BLK 8IN(20CM) USP10-0(M0.2) D/A CSC-6	H010201010101
7060G	ETHILON BLK 6IN(15CM) USP10-0(M0.2) S/A CS140-6	H010201010101
7061G	ETHILON BLK 6IN(15CM) USP10-0(M0.2) S/A CS160-6	H010201010101
7062G	ETHILON BLK 6IN(15CM) USP10-0(M0.2) S/A CSC-6	H010201010101
7770G	ETHILON BLK 12IN(30CM) USP10-0(M0.2) D/A TG140-6	H010201010101
9013G	ETHILON BLK 12IN(30CM) USP9-0(M0.3) D/A CS140-6	H010201010101
9033G	ETHILON BLK 12IN(30CM) USP10-0(M0.2) D/A CS140-8	H010201010101
9060G	ETHILON BLK 4IN(10CM) USP10-0(M0.2) S/A CS140-6	H010201010101
B7712	ETHILON BLK 12IN(30CM) USP5-0(M1) D/A S-14	H010201010101
B7714	ETHILON BLK 12IN(30CM) USP8-0(M0.4) D/A TG100-8	H010201010101
B7717	ETHILON BLK 12IN(30CM) USP9-0(M0.3) D/A TG140-8	H010201010101
B7718	ETHILON BLK 12IN(30CM) USP10-0(M0.2) D/A TG140-8	H010201010101
B7757	ETHILON BLK 6IN(15CM) USP10-0(M0.2) D/A TG160-6	H010201010101
B7769	ETHILON BLK 12IN(30CM) USP9-0(M0.3) D/A TG140-6	H010201010101
B7770	ETHILON BLK 12IN(30CM) USP10-0(M0.2) D/A TG140-6	H010201010101
B7780	ETHILON BLK 12IN(30CM) USP10-0(M0.2) D/A TG140-6	H010201010101

Product Code	Product Description	EMDN Code
B7781	ETHILON BLK 6IN(15CM) USP10-0(M0.2) S/A TG140-6	H010201010101
BN667	ETHILON BLK 18IN(45CM) USP6-0(M0.7) S/A C-3	H010201010101
BN668	ETHILON BLK 18IN(45CM) USP5-0(M1) S/A C-3	H010201010101
EB5133H	ETHILON BLK 12IN(30CM) USP7-0(M0.5) S/A GS-8	H010201010101
EF5130G	ETHILON BLK 12IN(30CM) USP10-0(M0.2) S/A GS-12	H010201010101
EH6573H	ETHILON BLK 10X18IN(45CM) USP2-0(M3) NON NDL	H010201010102
EH7136G	ETHILON WHT 18IN(45CM) USP4-0(M1.5) D/A S-4	H010201010101
EH7177H	ETHILON BLK 18IN(45CM) USP6-0(M0.7) S/A FS-3 VB	H010201010101
EH7436G	ETHILON BLK 2IN(5CM) USP11-0(M0.1) S/A BV50-3	H010201010101
EH7438G	ETHILON BLK 4IN(10CM) USP11-0(M0.1) S/A BV75-4	H010201010101
EH7444G	ETHILON BLK 4IN(10CM) USP10-0(M0.2) S/A BV75-4	H010201010101
EH7446H	ETHILON BLK 18IN(45CM) USP7-0(M0.5) S/A BV-1	H010201010101
EH7466E	ETHILON BLK 4IN(10CM) USP9-0(M0.3) D/A BV-2	H010201010101
EH7624BT	ETHILON BLK 30IN(75CM) USP0(M3.5) D/A STAW	H010201010101
EH7625BT	ETHILON BLK 30IN(75CM) USP2-0(M3) D/A STAW	H010201010101
EH7980G	ETHILON BLK 6IN(15CM) USP10-0(M0.2) S/A CS-35C	H010201010101
EH7981G	ETHILON BLK 6IN(15CM) USP9-0(M0.3) S/A CS-35C	H010201010101
EH7985G	ETHILON BLK 12IN(30CM) USP10-0(M0.2) D/A CS-35C	H010201010101
EH7990G	ETHILON BLK 6IN(15CM) USP10-0(M0.2) S/A CS-44C	H010201010101
EH7991G	ETHILON BLK 6IN(15CM) USP9-0(M0.3) S/A CS-44C	H010201010101
EH7995G	ETHILON BLK 12IN(30CM) USP10-0(M0.2) D/A CS-44C	H010201010101
EH7998G	ETHILON BLK 4IN(10CM) USP10-0(M0.2) S/A CSA-48C	H010201010101
F24005	ETHILON BLK 30IN(75CM) USP7-0(M0.5) S/A P-6 PRM	H010201010101
F2403	ETHILON BLK 30IN(75CM) USP6-0(M0.7) S/A C-3	H010201010101
F2412G	ETHILON BLK 30IN(75CM) USP5-0(M1) S/A C-3	H010201010101
F2412H	ETHILON BLK 30IN(75CM) USP5-0(M1) S/A C-3	H010201010101
F2429	ETHILON BLK 36IN(90CM) USP4-0(M1.5) S/A TS	H010201010101

Product Code	Product Description	EMDN Code
F2429H	ETHILON BLK 36IN(90CM) USP4-0(M1.5) S/A TS	H010201010101
F2430H	ETHILON BLK 36IN(90CM) USP3-0(M2) S/A TS	H010201010101
F2431H	ETHILON BLK 36IN(90CM) USP2-0(M3) S/A TS	H010201010101
F2433	ETHILON BLK 36IN(90CM) USP3-0(M2) S/A KS	H010201010101
F2434	ETHILON BLK 36IN(90CM) USP2-0(M3) S/A KS	H010201010101
F2442H	ETHILON BLK 36IN(90CM) USP1(M4) S/A TS	H010201010101
F2443	ETHILON BLK 36IN(90CM) USP1(M4) S/A KS	H010201010101
F2443H	ETHILON BLK 36IN(90CM) USP1(M4) S/A KS	H010201010101
F2445	ETHILON BLK 30IN(75CM) USP2-0(M3) D/A KS	H010201010101
F2446	ETHILON BLK 36IN(90CM) USP3-0(M2) S/A CP-1	H010201010101
F3224BH	ETHILON BLK 40IN(100CM) USP0(M3.5) S/A FS-1	H010201010101
F3269BH	ETHILON BLK 40IN(100CM) USP0(M3.5) S/A TS	H010201010101
F6364G	ETHILON BLK 6X20IN(50CM) USP2-0(M3) NON NDL	H010201010102
F6365G	ETHILON BLK 6X20IN(50CM) USP1(M4) NON NDL	H010201010102
F6366G	ETHILON BLK 6X20IN(50CM) USP2(M5) NON NDL	H010201010102
FG2850	ETHILON BLK 5IN(13CM) USP10-0(M0.2) S/A BV75-3	H010201010101
FG2851	ETHILON BLK 2IN(5CM) USP11-0(M0.15) S/A BV75-3	H010201010101
FG2880	ETHILON BLK 5IN(13CM) USP10-0(M0.2) S/A BV50-3	H010201010101
FG2881	ETHILON BLK 2IN(5CM) USP11-0(M0.15) S/A BV50-3	H010201010101
GEH7625T	ETHILON GRN 30IN(75CM) USP2-0(M3) D/A STAW	H010201010101
JM5140H	ETHILON BLK 18IN(45CM) USP6-0(M0.7) S/A PC-1 PRIME	H010201010101
MPE1696H	ETHILON BLK 18IN(45CM) USP7-0(M0.5) S/A P-1 PRIME MP	H010201010101
U7013	ETHILON BLK 6IN(15CM) USP10-0(M0.2) S/A CS140-6	H010201010101
W1600T	ETHILON BLK 18IN(45CM) USP6-0(M0.7) S/A P-6 PRM	H010201010101
W1601T	ETHILON BLK 18IN(45CM) USP5-0(M1) S/A P-6 PRIME	H010201010101
W1632BH	ETHILON BLK 30IN(75CM) USP2-0(M3) S/A CEC135-40 PRIME	H010201010101
W182	ETHILON BLK 2X40IN(100CM) USP3-0(M2) NON NDL	H010201010102

Product Code	Product Description	EMDN Code
W183	ETHILON BLK 2X40IN(100CM) USP2-0(M3) NON NDL	H010201010102
W184	ETHILON BLK 2X40IN(100CM) USP0(M3.5) NON NDL	H010201010102
W185	ETHILON BLK 2X40IN(100CM) USP1(M4) NON NDL	H010201010102
W1851T	ETHILON BLK 18IN(45CM) USP6-0(M0.7) S/A P-3 PRIME	H010201010101
W1852T	ETHILON BLK 18IN(45CM) USP5-0(M1) S/A P-3 PRIME	H010201010101
W1858BG	ETHILON BLK 18IN(45CM) USP5-0(M1) S/A PC-25 PRIME	H010201010101
W1859T	ETHILON BLK 18IN(45CM) USP6-0(M0.7) S/A PC-25 PRIME	H010201010101
W186	ETHILON BLK 2X40IN(100CM) USP2(M5) NON NDL	H010201010102
W2797	ETHILON BLK 2X20IN(50CM) USP1(M4) S/A KP-3 CONV + EA W/ RET TUB 40MM	H010201010101
W2850	ETHILON BLK 5IN(13CM) USP10-0(M0.2) S/A BV75-4	H010201010101
W2870	ETHILON BLK 5IN(13CM) USP10-0(M0.2) S/A BV75-3	H010201010101
W2881	ETHILON BLK 5IN(13CM) USP11-0(M0.1) S/A BV50-3	H010201010101
W511H	ETHILON BLK 18IN(45CM) USP6-0(M0.7) S/A FS-3 CONV	H010201010101
W558BG	ETHILON BLK 40IN(100CM) USP2-0(M3) S/A LR-60 CONV	H010201010101
W568	ETHILON BLK 40IN(100CM) USP2-0(M3) S/A MH-1	H010201010101
W689	ETHILON BLK 30IN(75CM) USP1(M4) D/A KP-3 CONV	H010201010101
W729	ETHILON BLK 60IN(150CM) USP1(M4) S/A CTXD LP	H010201010101
W736	ETHILON BLK 40IN(100CM) USP2-0(M3) S/A FSLY	H010201010101
W736G	ETHILON BLK 40IN(100CM) USP2-0(M3) S/A FSLY	H010201010101
W737	ETHILON BLK 40IN(100CM) USP0(M3.5) S/A CP	H010201010101
W738	ETHILON BLK 40IN(100CM) USP1(M4) S/A CPX	H010201010101
W738G	ETHILON BLK 40IN(100CM) USP1(M4) S/A CPX	H010201010101
W739	ETHILON BLK 60IN(150CM) USP0(M3.5) S/A MH-1 LP	H010201010101
W740	ETHILON BLK 60IN(150CM) USP0(M3.5) S/A CT LP	H010201010101
W740G	ETHILON BLK 60IN(150CM) USP0(M3.5) S/A CT LP	H010201010101
W741	ETHILON BLK 60IN(150CM) USP0(M3.5) S/A CTX LP	H010201010101
W743	ETHILON BLK 60IN(150CM) USP1(M4) S/A CT-1 LP	H010201010101

Product Code	Product Description	EMDN Code
W745	ETHILON BLK 40IN(100CM) USP1(M4) S/A MH-1	H010201010101
W747	ETHILON BLK 40IN(100CM) USP1(M4) S/A CT	H010201010101
W748	ETHILON BLK 60IN(150CM) USP1(M4) S/A CTX LP	H010201010101
W749	ETHILON BLK 40IN(100CM) USP1(M4) S/A CTX	H010201010101
W757	ETHILON BLK 79IN(200CM) USP1(M4) S/A V-39 LP	H010201010101
W768	ETHILON BLK 79IN(200CM) USP1(M4) S/A CTX LP	H010201010101
W795BG	ETHILON BLK 40IN(100CM) USP2-0(M3) S/A KP-3 CONV	H010201010101
W796BG	ETHILON BLK 40IN(100CM) USP0(M3.5) S/A KP-3 CONV	H010201010101
W797BG	ETHILON BLK 40IN(100CM) USP1(M4) S/A KP-3 CONV	H010201010101
W798BG	ETHILON BLK 40IN(100CM) USP2(M5) S/A KP-3 CONV	H010201010101