

English			
ETHICON_{LLC} a Johnson & Johnson company EU DECLARATION OF CONFORMITY			
Manufacturer's Name		Ethicon, LLC, Guaynabo	
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		100696245	
Product and Trade Name(s)		PERMA-HAND™ Braided Silk and Virgin Silk Non-Absorbable Sutures	
Product Code(s)/Product Range and Description		Refer to Attachment 1 and Attachment 2	
Intended Purpose		Silk 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		13910 Silk Suture	
EMDN Code		H010202020301: Silk with Needle H010202020302: Silk without Needle	
Basic UDI-DI value		Basic UDI-DI Device Name	Basic UDI-DI Device Model
		Silk Sterile Non-Absorbable Surgical Suture	Silk Suture
		0705031a011934W	
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 719650, issued by the Notified Body stated above, in accordance with Annex IX, Chapter II of the Medical Device Regulation (EU) 2017/745.			

English

ETHICON LLC

a *Johnson & Johnson* company

EU DECLARATION OF CONFORMITY

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	26-JUL-2023
Name/Title	Valerie Smith Beyer, Director Regulatory Affairs WCH Sutures		
Signature		Date	26-July-2023
Name/Title	Marjorie Medina, Senior Director Supply Chain Quality		
	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	
Manufacturer's Name	Ethicon, LLC
Technical Documentation Number	100696245

Suture Characteristics	Range
Suture Material (Absorbable/Non-Absorbable)	Non-Absorbable
Suture Gauge Size	0.4 – 7.0 (Metric)
Suture Length	30 cm – 180 cm
Suture Dyed/Undyed	Dyed / Undyed
Suture Color (If dyed)	Black / Blue
Coated/Uncoated	Coated / Uncoated
Multifilament/Monofilament	Multifilament
Accessories to suture type	N/A
Additional presentations	N/A
Needled/Non-Needled	Needled (also available with CONTROL RELEASE™ needles) and Non-needed
Number of Needles per Suture	Single Armed/Double Armed
Needle Material	420 SS, 455 SS, 4310 SS, ETHALLOY
Needle Coating	Silicone, CERBERUS, MULTIPASS
Needle Shape	Straight/Curve
Needle Color	Silver/Black
Needle Length	5 mm – 90 mm
Needle Wire Diameter	0.15 mm – 1.27 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	100696245
Product and Trade Name(s)	PERMA-HAND™ Braided Silk and Virgin Silk Non-Absorbable Sutures
Intended Purpose	Silk 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/PRODUCTS RANGE		
Product Code	Product Description	EMDN Code
1639H	SILK BLK 18IN(45CM) USP6-0(M0.7) S/A P-3 PRM	H010202020301
1675H	SILK BLK 18IN(45CM) USP6-0(M0.7) S/A PS-3 PRM	H010202020301
1676H	SILK BLK 18IN(45CM) USP5-0(M1) S/A PS-2 PRM	H010202020301
1780G	SILK BLK 18IN(45CM) USP6-0(M0.7) D/A S-14	H010202020301
18507G	SILK BLK 18IN(45CM) USP4-0(M1.5) S/A ST-4 MP	H010202020301
18529G	SILK BLK 18IN(45CM) USP4-0(M1.5) S/A DA VB	H010202020301
18530G	SILK BLK 18IN(45CM) USP3-0(M2) S/A DA VB	H010202020301
18534G	SILK BLK 18IN(45CM) USP4-0(M1.5) S/A DA-1 VB	H010202020301
639H	SILK BLK 18IN(45CM) USP6-0(M0.7) S/A P-1 PRM	H010202020301
681H	SILK BLK 18IN(45CM) USP6-0(M0.7) S/A FS-3	H010202020301
706H	SILK BLK 18IN(45CM) USP6-0(M0.7) D/A C-1	H010202020301

LIST OF PRODUCT CODES/PRODUCTS RANGE		
Product Code	Product Description	EMDN Code
711H	SILK BLK 12IN(30CM) USP6-0(M0.7) S/A C-3	H010202020301
735H	SILK BLK 12IN(30CM) USP4-0(M1.5) D/A C-3	H010202020301
765G	SILK BLK 18IN(45CM) USP6-0(M0.7) D/A G-7 PRM	H010202020301
766G	SILK BLK 18IN(45CM) USP7-0(M0.5) D/A G-7 PRM	H010202020301
768G	SILK BLK 18IN(45CM) USP7-0(M0.5) D/A G-6 PRM	H010202020301
769G	SILK BLK 18IN(45CM) USP6-0(M0.7) D/A G-6 PRM	H010202020301
780G	SILK BLK 18IN(45CM) USP6-0(M0.7) D/A G-1 PRM	H010202020301
783G	SILK BLK 18IN(45CM) USP4-0(M1.5) D/A G-3 PRM	H010202020301
786G	SILK BLK 18IN(45CM) USP6-0(M0.7) S/A G-1 PRM	H010202020301
8PA3544YD	SILK BLK 8X18IN(45CM) USP3-0(M2) S/A TF PLUS CR	H010202020301
C016G	SILK BLK 8X30IN(75CM) USP2-0(M3) S/A SH CR	H010202020301
C017G	SILK BLK 8X30IN(75CM) USP3-0(M2) S/A SH CR	H010202020301
C3D	SILK BLK 8X18IN(45CM) USP3-0(M2) S/A SH-1 PLUS CR	H010202020301
C53D	SILK BLK 8X18IN(45CM) USP3-0(M2) S/A RB-1 PLUS CR	H010202020301
C84D	SILK BLK 8X18IN(45CM) USP4-0(M1.5) S/A TF PLUS CR	H010202020301
ECC3543G	SILK BLK 18IN(45CM) USP7-0(M0.5) D/A TG140-8	H010202020301
EH6715E	SILK BLK 6X18IN(45CM) USP0(M3.5) NON NDL	H010202020302
EH6717E	SILK BLK 6X18IN(45CM) USP2(M5) NON NDL	H010202020302
EH6722E	SILK BLK 12X18IN(45CM) USP4-0(M1.5) NON NDL	H010202020302
EH6723E	SILK BLK 12X18IN(45CM) USP3-0(M2) NON NDL	H010202020302
EH6834E	SILK BLK 2X27IN(70CM) USP2-0(M3) NON NDL	H010202020302
EH6835E	SILK BLK 2X27IN(70CM) USP0(M3.5) NON NDL	H010202020302
EH6836E	SILK BLK 2X27IN(70CM) USP1(M4) NON NDL	H010202020302
EH6837E	SILK BLK 2X27IN(70CM) USP2(M5) NON NDL	H010202020302
EH6839E	SILK BLK 2X27IN(70CM) USP5(M7) NON NDL	H010202020302
EH7434G	SILK BLK 2X18IN(45CM) USP3-0(M2) S/A BBS	H010202020301
EH7435G	SILK BLK 12IN(30CM) USP6-0(M0.7) S/A G-6 PRM	H010202020301
EH7440G	SILK BLK 18IN(45CM) USP5-0(M1) D/A S-14	H010202020301

LIST OF PRODUCT CODES/PRODUCTS RANGE		
Product Code	Product Description	EMDN Code
EH7457G	VIRGIN SILK BLU 12IN(30CM) USP8-0(M0.4) S/A G-8	H010202020301
EH7464G	SILK BLK 12IN(30CM) USP7-0(M0.5) S/A G-6 PRM	H010202020301
EH7724H	SILK BLK 30IN(75CM) USP2-0(M3) S/A KS	H010202020301
EH7983G	VIRGIN SILK BLU 12IN(30CM) USP8-0(M0.4) D/A CS-35C	H010202020301
F2228	SILK BLK 30IN(75CM) USP3-0(M2) S/A TS	H010202020301
F2229	SILK BLK 30IN(75CM) USP3-0BIS(M2.5) S/A TS	H010202020301
F2242	SILK BLK 30IN(75CM) USP1(M4) S/A KS	H010202020301
F623	SILK BLK 30IN(75CM) USP3-0BIS(M2.5) S/A KS	H010202020301
F711	SILK BLK 18IN(45CM) USP6-0(M0.7) S/A C-3	H010202020301
F781	SILK BLK 18IN(45CM) USP7-0(M0.5) S/A G-6 PRM	H010202020301
F783	SILK BLK 18IN(45CM) USP4-0(M1.5) D/A C-3	H010202020301
FK802	SILK BLK 18IN(45CM) USP6-0(M0.7) S/A CC MP	H010202020301
FK803	SILK BLK 18IN(45CM) USP7-0(M0.5) S/A CC MP	H010202020301
FK870	SILK BLK 30IN(75CM) USP5-0(M1) S/A RB-1	H010202020301
FK889	SILK BLK 30IN(75CM) USP6-0(M0.7) S/A CC-1 MP	H010202020301
FV768	VIRGIN SILK BLU 18IN(45CM) USP8-0(M0.4) D/A G-6 PRM	H010202020301
FV769	VIRGIN SILK BLU 18IN(45CM) USP8-0(M0.4) S/A G-6 PRM	H010202020301
FV7771	VIRGIN SILK BLU 18IN(45CM) USP8-0(M0.4) D/A TG140-8	H010202020301
FW529	SILK BLK 30IN(75CM) USP6-0(M0.7) S/A PC-3 PRM	H010202020301
FW587	SILK BLK 30IN(75CM) USP3-0(M2) S/A RS MP	H010202020301
FW622	SILK BLK 40IN(100CM) USP3-0(M2) S/A KS	H010202020301
FW775	SILK BLK 40IN(100CM) USP2-0(M3) S/A KS	H010202020301
K802H	SILK BLK 18IN(45CM) USP6-0(M0.7) S/A BV-1	H010202020301
K803H	SILK BLK 12IN(30CM) USP7-0(M0.5) S/A BV-1	H010202020301
K804H	SILK BLK 30IN(75CM) USP7-0(M0.5) D/A BV-1	H010202020301
K831H	SILK BLK 30IN(75CM) USP4-0(M1.5) S/A SH MP	H010202020301
K836H	SILK BLK 30IN(75CM) USP2(M5) S/A SH	H010202020301
K842H	SILK BLK 30IN(75CM) USP3-0(M2) S/A MH MP	H010202020301

LIST OF PRODUCT CODES/PRODUCTS RANGE		
Product Code	Product Description	EMDN Code
K846H	SILK BLK 30IN(75CM) USP2(M5) S/A CT-1 PLUS	H010202020301
K853H	SILK BLK 30IN(75CM) USP2-0(M3) S/A ST	H010202020301
K854H	SILK BLK 30IN(75CM) USP0(M3.5) S/A ST	H010202020301
K861H	SILK BLK 30IN(75CM) USP4-0(M1.5) S/A ST-4 MP	H010202020301
K889H	SILK BLK 30IN(75CM) USP6-0(M0.7) S/A C-1	H010202020301
K890H	SILK BLK 30IN(75CM) USP5-0(M1) S/A C-1	H010202020301
K936H	SILK BLK 30IN(75CM) USP3-0(M2) D/A V-5 MP	H010202020301
K951H	SILK BLK 30IN(75CM) USP5-0(M1) S/A V-5 MP	H010202020301
N271H	SILK BLK 18IN(45CM) USP5-0(M1) S/A TF-4	H010202020301
N272H	SILK BLK 18IN(45CM) USP4-0(M1.5) S/A TF-4	H010202020301
P7228H	SILK BLK 30IN(75CM) USP2(M5) S/A FSLX	H010202020301
P853H	SILK BLK 36IN(90CM) USP2-0(M3) S/A ST	H010202020301
P854H	SILK BLK 36IN(90CM) USP0(M3.5) S/A ST	H010202020301
SA63T	SILK BLK 17X18IN(45CM) USP4-0(M1.5) NON NDL	H010202020302
SA64T	SILK BLK 17X18IN(45CM) USP3-0(M2) NON NDL	H010202020302
SA65T	SILK BLK 17X18IN(45CM) USP2-0(M3) NON NDL	H010202020302
SA66G	SILK BLK 17X18IN(45CM) USP0(M3.5) NON NDL	H010202020302
W191	SILK BLK 71IN(180CM) USP4-0(M1.5) NON NDL	H010202020302
W192	SILK BLK 71IN(180CM) USP3-0(M2) NON NDL	H010202020302
W192G	SILK BLK 71IN(180CM) USP3-0(M2) NON NDL	H010202020302
W193	SILK BLK 71IN(180CM) USP2-0(M3) NON NDL	H010202020302
W193G	SILK BLK 71IN(180CM) USP2-0(M3) NON NDL	H010202020302
W194	SILK BLK 71IN(180CM) USP0(M3.5) NON NDL	H010202020302
W194G	SILK BLK 71IN(180CM) USP0(M3.5) NON NDL	H010202020302
W195	SILK BLK 71IN(180CM) USP1(M4) NON NDL	H010202020302
W195G	SILK BLK 71IN(180CM) USP1(M4) NON NDL	H010202020302
W196	SILK BLK 71IN(180CM) USP2(M5) NON NDL	H010202020302
W196G	SILK BLK 71IN(180CM) USP2(M5) NON NDL	H010202020302

LIST OF PRODUCT CODES/PRODUCTS RANGE		
Product Code	Product Description	EMDN Code
W199	SILK BLK 71IN(180CM) USP4(M6) NON NDL	H010202020302
W199G	SILK BLK 71IN(180CM) USP4(M6) NON NDL	H010202020302
W202	SILK BLK 17X18IN(45CM) USP3-0(M2) NON NDL	H010202020302
W203	SILK BLK 17X18IN(45CM) USP2-0(M3) NON NDL	H010202020302
W204	SILK BLK 17X18IN(45CM) USP0(M3.5) NON NDL	H010202020302
W205	SILK BLK 17X18IN(45CM) USP1(M4) NON NDL	H010202020302
W211	SILK BLK 13X24IN(60CM) USP4-0(M1.5) NON NDL	H010202020302
W212	SILK BLK 13X24IN(60CM) USP3-0(M2) NON NDL	H010202020302
W213	SILK BLK 13X24IN(60CM) USP2-0(M3) NON NDL	H010202020302
W214	SILK BLK 13X24IN(60CM) USP0(M3.5) NON NDL	H010202020302
W215	SILK BLK 13X24IN(60CM) USP1(M4) NON NDL	H010202020302
W222	SILK BLK 10X30IN(75CM) USP3-0(M2) NON NDL	H010202020302
W223	SILK BLK 10X30IN(75CM) USP2-0(M3) NON NDL	H010202020302
W224	SILK BLK 10X30IN(75CM) USP0(M3.5) NON NDL	H010202020302
W225	SILK BLK 10X30IN(75CM) USP1(M4) NON NDL	H010202020302
W260	SILK BLK 30IN(75CM) USP3-0(M2) S/A CP-80 CONV	H010202020301
W261	SILK BLK 30IN(75CM) USP2-0(M3) S/A CP-80 CONV	H010202020301
W261G	SILK BLK 30IN(75CM) USP2-0(M3) S/A CP-80 CONV	H010202020301
W529H	SILK BLK 18IN(45CM) USP6-0(M0.7) S/A PC-3 PRM	H010202020301
W593	SILK BLK 18IN(45CM) USP6-0(M0.7) S/A BV-1	H010202020301
W606	SILK BLK/IVY 4X18IN(45CM) USP4-0(M1.5) S/A PC-3 PRM	H010202020301
W606G	SILK 3BLK/1UD 18IN(45CM) USP4-0(M1.5) S/A PC-3 PRM MP	H010202020301
W6327	SILK BLK 6X14IN(35CM) USP2-0(M3) S/A SH	H010202020301
W640	SILK BLK 15IN(38CM) USP5-0(M1) D/A FS-3 CONV	H010202020301
W641	SILK BLK 15IN(38CM) USP4-0(M1.5) D/A FS-3 CONV	H010202020301
W812	SILK BLK 18IN(45CM) USP6-0(M0.7) S/A G-1 PRM	H010202020301
W815	SILK BLK 18IN(45CM) USP6-0(M0.7) D/A G-1 PRM	H010202020301
W816	SILK IVY 18IN(45CM) USP4-0(M1.5) D/A C-3	H010202020301

LIST OF PRODUCT CODES/PRODUCTS RANGE		
Product Code	Product Description	EMDN Code
W888	SILK BLK 18IN(45CM) USP6-0(M0.7) D/A S-14	H010202020301
W562H	SILK BLK 30IN(75CM) USP1(M4) S/A LR-60 CONV	H010202020301