

English			
 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		100696210	
Product and Trade Name(s)		Coated VICRYL™ Plus Antibacterial (Polyglactin 910) Sterile Synthetic Absorbable Suture	
Product Code(s)/Product Range and Description		Refer to Attachment 1 and Attachment 2	
Intended Purpose		Coated VICRYL™ Plus Antibacterial Suture is indicated for use in general soft tissue approximation and/or ligation, except for ophthalmic, cardiovascular and neurological tissues.	
Classification		Class III (Annex VII, Rules 8 and 14)	
GMDN Code		45401, Polyester suture, bioabsorbable, multifilament, antimicrobial	
EMDN Code		H010101040201 - Polyglycolic Acid with Lactic Acid with Antibacterial Multifilament with Needle	
Basic UDI-DI value		Basic UDI-DI Device Name	Basic UDI-DI Device Model
		Vicryl Plus Antibacterial Polyglactin 910 Braided Absorbable Suture	Vicryl Plus Antibacterial
0705031a007935M			
This EU Declaration of Conformity is issued under the sole responsibility of the Manufacturer.			
We, Johnson & Johnson International, hereby declare the above listed Medical Device(s) complies with Medical Device Regulation (EU) 2017/745.			
This declaration is made on the basis of:			

English

ETHICON

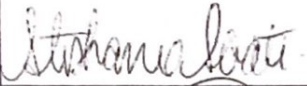
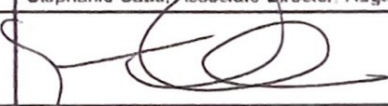
a Johnson & Johnson company

EU DECLARATION OF CONFORMITY

EU Technical Documentation Assessment Certificate Number MDR 719661, 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	14-Mar-2023
Name/Title	Stephanie Saati, Associate Director, Regulatory Affairs		
Signature		Date	16-Mar-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 <i>Johnson & Johnson</i> company EU DECLARATION OF CONFORMITY	
Manufacturer's Name	Ethicon LLC
Technical Documentation Number	100696210

Suture Characteristics	Range
Suture Material (Absorbable/Non-Absorbable)	Absorbable
Suture Gauge Size	1.0 – 5.0 (Metric)
Suture Length	45 cm – 150 cm
Suture Dyed / Undyed	Dyed / Undyed
Suture Color (If dyed)	Violet
Suture Coated / Uncoated (Coating material)	Coated (Copolymer of glycolide and lactide, calcium stearate)
Multifilament / Monofilament	Multifilament
Contains Antimicrobials (Yes/No)	Yes
Triclosan Maximum Levels (µg/m)	≤ 275 µg/m
Accessories to suture type	N/A
Suture Needled / Non-Needled	Needled (including CONTROL RELEASE)
Number of Needles per Suture	Single Armed/Double Armed
Needle Material	420 SS, 4310 SS, ETHALLOY
Needle Coating	Silicone, MULTIPASS, CERBERUS
Needle Shape	Straight / Curve
Needle Length	10 mm – 80 mm
Needle Color	Silver / Black
Needle Wire Diameter	0.305 mm – 1.550 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	100696210
Product and Trade Name(s)	Coated VICRYL™ Plus Antibacterial (Polyglactin 910) Sterile Synthetic Absorbable Suture
Intended Purpose	Coated VICRYL™ Plus Antibacterial Suture is indicated for use in general soft tissue approximation and/or ligation, except for ophthalmic, cardiovascular and neurological tissues.

LIST OF PRODUCT CODES		
Product Code	Product Description	EMDN Code
MIC507E	VICRYL PLUSVIO44IN(110CM)USP2-0(M3)S/A TN	H010101040201
MIC509E	VICRYL PLUSVIO44IN(110CM)USP0(M3.5)S/A TN	H010101040201
VCP1088H	VICRYL PLUSVIO27IN(70CM)USP1(M4) S/ACPA	H010101040201
VCP115H	VICRYL PLUSVIO27IN(70CM)USP0(M3.5)S/A UCL	H010101040201
VCP133H	VICRYL PLUSVIO27IN(70CM)USP5-0(M1)S/A TF-1 PLUS	H010101040201
VCP1408E	VICRYL PLUSVIO60IN(150CM)USP1(M4) S/ACT LP	H010101040201
VCP1408T	VICRYL PLUSVIO60IN(150CM)USP1(M4) S/ACT LP	H010101040201
VCP1410E	VICRYL PLUSVIO60IN(150CM)USP1(M4) S/ACCS LP	H010101040201
VCP1410T	VICRYL PLUSVIO60IN(150CM)USP1(M4) S/ACCS LP	H010101040201
VCP1428E	VICRYL PLUSVIO60IN(150CM)USP1(M4) S/ACTX LP	H010101040201
VCP1428T	VICRYL PLUSVIO60IN(150CM)USP1(M4) S/ACTX LP	H010101040201
VCP2406G	VICRYL PLUSVIO47IN(120CM)USP3-0(M2)S/A SH PLUS	H010101040201
VCP2543D	VICRYL PLUSVIO8X18IN(45CM) USP4-0(M1.5) S/A	H010101040201
VCP2576G	VICRYL PLUSVIO5X27IN(70CM) USP1(M4)S/A MO-5 CR	H010101040201
VCP2593H	VICRYL PLUSVIO36IN(90CM)USP2-0(M3)D/A UR-6	H010101040201

LIST OF PRODUCT CODES		
Product Code	Product Description	EMDN Code
VCP2594H	VICRYL PLUSVIO36IN(90CM)USP0(M3.5)S/A UR-6	H010101040201
VCP2672H	VICRYL PLUSUD27IN(70CM)USP5-0(M1)S/A TF PLUS	H010101040201
VCP303H	VICRYL PLUSVIO27IN(70CM)USP5-0(M1)S/A RB-1 PLUS	H010101040201
VCP308H	VICRYL PLUSUD27IN(70CM)USP3-0(M2)S/A MF	H010101040201
VCP368G	VICRYL PLUSVIO36IN(90CM)USP2(M5) S/AMO-75	H010101040201
VCP375H	VICRYL PLUSVIO27IN(70CM)USP2-0(M3)S/A UR-5	H010101040201
VCP376H	VICRYL PLUSVIO27IN(70CM)USP0(M3.5)S/A UR-5	H010101040201
VCP433H	VICRYL PLUSUD27IN(70CM)USP5-0(M1)S/A RB-2	H010101040201
VCP434H	VICRYL PLUSUD27IN(70CM)USP4-0(M1.5)S/A RB-2	H010101040201
VCP581G	VICRYL PLUSVIO27IN(70CM)USP2-0(M3)S/A XLH	H010101040201
VCP584G	VICRYL PLUSVIO47IN(120CM)USP1(M4) S/AXLH	H010101040201
VCP5891G	VICRYL PLUSVIO36IN(90CM)USP1(M4) S/AXLH	H010101040201
VCP602H	VICRYL PLUSVIO27IN(70CM)USP2-0(M3)S/A UR-6	H010101040201
VCP603H	VICRYL PLUSVIO27IN(70CM)USP0(M3.5)S/A UR-6	H010101040201
VCP649G	VICRYL PLUSVIO4X27IN(70CM) USP2(M5)S/A TP-1	H010101040201
VCP663H	VICRYL PLUSUD27IN(70CM)USP3-0(M2)S/A KS	H010101040201
VCP664H	VICRYL PLUSUD27IN(70CM)USP2-0(M3)S/A KS	H010101040201
VCP694H	VICRYL PLUSUD27IN(70CM)USP0(M3.5)S/A OS-4	H010101040201
VCP695H	VICRYL PLUSUD27IN(70CM)USP1(M4) S/AOS-4	H010101040201
VCP7340D	VICRYL PLUSVIO8X18IN(45CM) USP4-0(M1.5) S/A	H010101040201
VCP734D	VICRYL PLUSVIO8X18IN(45CM) USP4-0(M1.5) S/A	H010101040201
VCP773D	VICRYL PLUSVIO8X18IN(45CM) USP4-0(M1.5) S/A	H010101040201
VCP794D	VICRYL PLUSVIO8X18IN(45CM) USP4-0(M1.5) S/A	H010101040201
VCP7980D	VICRYL PLUSVIO8X27IN(70CM) USP4-0(M1.5) S/A	H010101040201
VCP798G	VICRYL PLUSVIO8X27IN(70CM) USP4-0(M1.5) S/A	H010101040201
VCP799D	VICRYL PLUSVIO8X27IN(70CM) USP4-0(M1.5) S/A	H010101040201
VCP829E	VICRYL PLUSVIO60IN(150CM)USP1(M4) S/AV-40 LP	H010101040201
VCP829T	VICRYL PLUSVIO60IN(150CM)USP1(M4) S/AV-40 LP	H010101040201
VCP9067H	VICRYL PLUSVIO27IN(70CM)USP4-0(M1.5)S/A C-1	H010101040201
VCP9221H	VICRYL PLUSVIO27IN(70CM)USP0(M3.5)S/A ASH-35	H010101040201
VCP925H	VICRYL PLUSVIO27IN(70CM)USP5-0(M1)S/A TF PLUS	H010101040201
VCP9289G	VICRYL PLUSVIO40IN(100CM)USP1(M4) S/AMO-80	H010101040201
VCP9335H	VICRYL PLUSVIO27IN(70CM)USP1(M4) S/AV-38	H010101040201

LIST OF PRODUCT CODES		
Product Code	Product Description	EMDN Code
VCP9362H	VICRYL PLUSVIO27IN(70CM)USP1(M4) S/AV-30	H010101040201
VCP9391G	VICRYL PLUSVIO40IN(100CM)USP1(M4) S/ABP-5	H010101040201
VCP9410H	VICRYL PLUSVIO18IN(45CM)USP4-0(M1.5)S/A SC-1	H010101040201
VCP9507H	VICRYL PLUSUD18IN(45CM)USP3-0(M2)S/A PC-3 PRM	H010101040201
VCP9531H	VICRYL PLUSUD27IN(70CM)USP3-0(M2)S/A PCLX PRM	H010101040201
VCP9532H	VICRYL PLUSUD27IN(70CM)USP2-0(M3)S/A PCLX PRM	H010101040201
VCP9571H	VICRYL PLUSUD27IN(70CM)USP3-0(M2)S/A PC-5 PRM	H010101040201
VCP9582H	VICRYL PLUSUD27IN(70CM)USP2-0(M3)S/A PC-25	H010101040201
VCP9982H	VICRYL PLUSUD18IN(45CM)USP5-0(M1)S/A RB-2	H010101040201
VCP9991E	VICRYL PLUSVIO36IN(90CM)USP1(M4) S/ACTXD	H010101040201
VCP9991T	VICRYL PLUSVIO36IN(90CM)USP1(M4) S/ACTXD	H010101040201
VCP9996E	VICRYL PLUSVIO36IN(90CM)USP0(M3.5)S/A CTD	H010101040201
VCP9996T	VICRYL PLUSVIO36IN(90CM)USP0(M3.5)S/A CTD	H010101040201
VCP9997E	VICRYL PLUSVIO36IN(90CM)USP1(M4) S/ACTD	H010101040201
VCP9997T	VICRYL PLUSVIO36IN(90CM)USP1(M4) S/ACTD	H010101040201