

English



EU DECLARATION OF CONFORMITY

Manufacturer's Name	Ethicon LLC								
Manufacturer's Address	475 C Street Los Frailes Industrial Park Suite 401 Guaynabo, PR 00969 USA								
Manufacturer's Single Registration Number (SRN)	US-MF-000013111								
Authorized Representative's Name and Address	Johnson & Johnson MEDICAL GmbH Robert-Koch-Str. 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	100853329								
Product and Trade Name(s)	VICRYL RAPIDE™ (Polyglactin 910) Synthetic Absorbable Suture								
Product Code(s)/Product Range and Description	Refer to Attachment 1 for Suture Product Range Refer to Attachment 2 for list of Product Codes and Description								
Intended Purpose	VICRYL RAPIDE™ Suture is intended for use in soft tissue approximation where only short-term wound support is required and where the rapid absorption of the suture would be beneficial. Due to its absorption profile VICRYL RAPIDE™ Suture is useful for skin closure, particularly in paediatric surgery, episiotomies, circumcision, and closure of oral mucosa. VICRYL RAPIDE™ Suture is also successfully used in ophthalmic surgery for conjunctival sutures.								
Classification	Class III (Annex VIII, Rule 8)								
GMDN Code	17471(Polyester suture, bioabsorbable, multifilament)								
EMDN Code	H0101010299 - Multifilament Absorbable Synthetic Sutures – Others								
Basic UDI-DI value	<table><tr><th>Basic UDI-DI Device Name</th><th>Basic UDI-DI Device Model</th><th>Basic UDI-DI</th></tr><tr><td>VICRYL RAPIDE (Polyglactin 910) Synthetic Absorbable Suture</td><td>Vicryl Rapide</td><td>0705031a012084J</td></tr></table>			Basic UDI-DI Device Name	Basic UDI-DI Device Model	Basic UDI-DI	VICRYL RAPIDE (Polyglactin 910) Synthetic Absorbable Suture	Vicryl Rapide	0705031a012084J
Basic UDI-DI Device Name	Basic UDI-DI Device Model	Basic UDI-DI							
VICRYL RAPIDE (Polyglactin 910) Synthetic Absorbable Suture	Vicryl Rapide	0705031a012084J							
Common Specifications	Common Specifications have not been issued.								

English



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

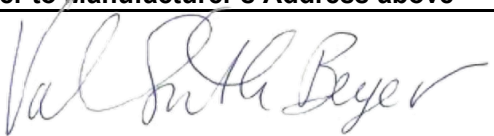
We, Ethicon, LLC, hereby declare the above listed Medical Device(s) complies with Medical Device Regulation (EU) 2017/745.

This declaration is made on the basis of:

EU Technical Documentation Assessment Certificate Number MDR 719664, 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	25-JAN-2023
Name/Title	Valerie Smith Beyer, Director, Regulatory Affairs		
Signature		Date	26-JAN-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

	
EU DECLARATION OF CONFORMITY	
Manufacturer's Name	Ethicon LLC
Technical Documentation Number	100853329

Suture Characteristics	Range
Suture Material (Absorbable/Non-Absorbable)	Absorbable
Suture Gauge Size	0.4 – 4.0 (Metric)
Suture Length	30 cm – 150 cm
Suture Dyed/Undyed	Dyed / Undyed
Suture Color (If dyed)	Violet
Coated/Uncoated	Coated
Multifilament/Monofilament	Multifilament
Accessories to suture type	N/A
Needled/Non-Needled	Needled / Non-Needled
Number of Needles per Suture	Single Armed / Double Armed
Needle Material	420 SS, 4310 SS, 4310 FB SS and ETHALLOY
Needle Coating	Silicone, MULTIPASS, CERBERUS
Needle Shape	Straight / Curve
Needle Color	Silver / Black
Needle Length	5.5 mm – 60 mm
Needle Wire Diameter	0.15 mm – 1.27 mm

ATTACHMENT 2

Product Codes and Descriptions

	
EU DECLARATION OF CONFORMITY	
Manufacturer's Name	Ethicon LLC
Technical Documentation Number	100853329
Product and Trade Names(s)	VICRYL RAPIDE™ (Polyglactin 910) Synthetic Absorbable Suture
Intended Purpose	VICRYL RAPIDE™ Suture is intended for use in soft tissue approximation where only short-term wound support is required and where the rapid absorption of the suture would be beneficial. Due to its absorption profile VICRYL RAPIDE™ Suture is useful for skin closure, particularly in paediatric surgery, episiotomies, circumcision, and closure of oral mucosa. VICRYL RAPIDE™ Suture is also successfully used in ophthalmic surgery for conjunctival sutures.

LIST OF PRODUCT CODES	
Product Code	Product Description
AA1673H	VICRYL RAP UD 27IN(70CM) USP3-0(M2) S/A KS
AA1674G	VICRYL RAP UD 27IN(70CM) USP2-0(M3) S/A KS
BA1673H	VICRYL RAP UD 27IN(70CM) USP4-0(M1.5) S/A ST-4
BH1643H	VICRYL RAP UD 18IN(45CM) USP4-0(M1.5) S/A SC-1
EC1534G	VICRYL RAP VIO 12IN(30CM) USP6-0(M0.7) S/A TG140-8

FH1642H	VICRYL RAP UD 18IN(45CM) USP4-0(M1.5) S/A FS-2
MPVR32H	VICRYL RAP VIO 18IN(45CM) USP6-0(M0.7) S/A P-1 PRM MP
MPVR4260H	VICRYL RAP UD 30IN(75CM) USP4-0(M1.5) S/A PS-2 PRM MP
MPVR4270H	VICRYL RAP UD 30IN(75CM) USP3-0(M2) S/A PS-2 PRM MP
MPVR489H	VICRYL RAP UD 27IN(70CM) USP6-0(M0.7) S/A P-1 PRM MP
MPVR9913H	VICRYL RAP UD 18IN(45CM) USP6-0(M0.7) S/A P-1 PRM MP
MPVR9915H	VICRYL RAP UD 18IN(45CM) USP5-0(M1) S/A P-1 PRM MP
MPVR9918H	VICRYL RAP UD 27IN(70CM) USP4-0(M1.5) S/A PC-3 PRM MP
MPVR9932H	VICRYL RAP UD 27IN(70CM) USP3-0(M2) S/A PS PRM MP
V1210G	VICRYL RAP VIO 12IN(30CM) USP8-0(M0.4) S/A GS-9
V1211G	VICRYL RAP VIO 12IN(30CM) USP7-0(M0.5) S/A GS-9
V1220G	VICRYL RAP VIO 12IN(30CM) USP8-0(M0.4) S/A GS-12
V2140H	VICRYL RAP UD 27IN(70CM) USP4-0(M1.5) S/A RB-1 PLUS
V32H	VICRYL RAP VIO 18IN(45CM) USP6-0(M0.7) S/A P-1 PRM
V38G	VICRYL RAP VIO 18IN(45CM) USP7-0(M0.5) D/A GS-9
V39G	VICRYL RAP VIO 12IN(30CM) USP8-0(M0.4) D/A GS-9
V401H	VICRYL RAP UD 36IN(90CM) USP1(M4) S/A UR-5
V4260H	VICRYL RAP UD 27IN(70CM) USP4-0(M1.5) S/A PS-2 PRM
V4270H	VICRYL RAP UD 27IN(70CM) USP3-0(M2) S/A PS-2 PRM
V4970H	VICRYL RAP UD 18IN(45CM) USP3-0(M2) S/A PS-2 PRM
V6830H	VICRYL RAP UD 18IN(45CM) USP3-0(M2) S/A PS-1 PRM
V70H	VICRYL RAP UD 36IN(90CM) USP1(M4) S/A CT-1 PLUS
V9360H	VICRYL RAP UD 27IN(70CM) USP3-0(M2) S/A PS-1 PRM
V9590H	VICRYL RAP UD 36IN(90CM) USP1(M4) S/A CT PLUS
VA1673H	VICRYL RAP UD 27IN(70CM) USP2-0(M3) S/A UR-5
VC532H	VICRYL RAP UD 54IN(135CM) USP2-0(M3) D/A CT-1,CP-1
VF2257	VICRYL RAP UD 18IN(45CM) USP4-0(M1.5) S/A J-1
VF2260	VICRYL RAP UD 18IN(45CM) USP3-0(M2) S/A X-1
VR2216	VICRYL RAP UD 36IN(90CM) USP1(M4) S/A V-37
VR2217	VICRYL RAP UD 36IN(90CM) USP2-0(M3) S/A V-34

VR2238	VICRYL RAP UD 30IN(75CM) USP4-0(M1.5) S/A TS
VR2239	VICRYL RAP UD 30IN(75CM) USP3-0(M2) S/A TS
VR2240	VICRYL RAP UD 30IN(75CM) USP2-0(M3) S/A TS
VR2251	VICRYL RAP UD 30IN(75CM) USP4-0(M1.5) S/A FS-1
VR2252	VICRYL RAP UD 30IN(75CM) USP3-0(M2) S/A FS-1
VR2253	VICRYL RAP UD 30IN(75CM) USP2-0(M3) S/A FS-1
VR2275	VICRYL RAP UD 18IN(45CM) USP4-0(M1.5) S/A DT-6
VR2279	VICRYL RAP UD 30IN(75CM) USP4-0(M1.5) S/A V-4
VR2280	VICRYL RAP UD 30IN(75CM) USP3-0(M2) S/A V-4
VR2285	VICRYL RAP UD 36IN(90CM) USP3-0(M2) S/A FSL
VR2286	VICRYL RAP UD 36IN(90CM) USP2-0(M3) S/A FSL
VR2287	VICRYL RAP UD 36IN(90CM) USP0(M3.5) S/A FSL
VR2289	VICRYL RAP UD 30IN(75CM) USP5-0(M1) S/A C-3
VR2290	VICRYL RAP UD 30IN(75CM) USP4-0(M1.5) S/A C-3
VR2293	VICRYL RAP UD 30IN(75CM) USP5-0(M1) S/A CC-1
VR2294	VICRYL RAP UD 30IN(75CM) USP4-0(M1.5) S/A FS-3
VR2295	VICRYL RAP UD 30IN(75CM) USP3-0(M2) S/A FS-3
VR2296	VICRYL RAP UD 30IN(75CM) USP5-0(M1) S/A FS-3
VR2297	VICRYL RAP UD 30IN(75CM) USP4-0(M1.5) S/A FS-2
VR2298	VICRYL RAP UD 30IN(75CM) USP3-0(M2) S/A FS-2
VR2299	VICRYL RAP UD 30IN(75CM) USP2-0(M3) S/A FS-2
VR3100	VICRYL RAP UD 30IN(75CM) USP4-0(M1.5) S/A SH-1 PLUS VB
VR3110	VICRYL RAP UD 30IN(75CM) USP3-0(M2) S/A SH-1 PLUS VB
VR489	VICRYL RAP UD 30IN(75CM) USP6-0(M0.7) S/A P-1 PRM MP
VR500	VICRYL RAP VIO 12IN(30CM) USP7-0(M0.5) S/A GS-9
VR501	VICRYL RAP VIO 12IN(30CM) USP8-0(M0.4) S/A GS-9
VR1213H	VICRYL RAP UD 30IN(75CM) USP5-0(M1) S/A RB-1
VR1214H	VICRYL RAP UD 30IN(75CM) USP4-0(M1.5) S/A RB-1 PLUS
VR1215H	VICRYL RAP UD 30IN(75CM) USP3-0(M2) S/A RB-1 PLUS
VR1252H	VICRYL RAP UD 30IN(75CM) USP3-0(M2) S/A FS-1

VRI253H	VICRYL RAP UD 30IN(75CM) USP2-0(M3) S/A FS-1
VRI290H	VICRYL RAP UD 18IN(45CM) USP4-0(M1.5) S/A C-3
VRI311H	VICRYL RAP UD 30IN(75CM) USP3-0(M2) S/A SH-1 PLUS
VRI312H	VICRYL RAP UD 30IN(75CM) USP2-0(M3) S/A SH-1 PLUS
VRI322H	VICRYL RAP UD 30IN(75CM) USP3-0(M2) S/A MH
VRI323H	VICRYL RAP UD 30IN(75CM) USP2-0(M3) S/A MH
VRI324H	VICRYL RAP UD 30IN(75CM) USP0(M3.5) S/A MH PLUS
VRI381H	VICRYL RAP UD 27IN(70CM) USP0(M3.5) S/A UR-4
VRI382H	VICRYL RAP UD 30IN(75CM) USP1(M4) S/A UR-4
VRI415H	VICRYL RAP UD 30IN(75CM) USP4-0(M1.5) S/A SH
VRI416H	VICRYL RAP UD 30IN(75CM) USP3-0(M2) S/A SH PLUS
VRI417H	VICRYL RAP UD 30IN(75CM) USP2-0(M3) S/A SH PLUS
VRI66H	VICRYL RAP UD 30IN(75CM) USP0(M3.5) S/A SH PLUS
VS3530E	VICRYL RAP UD 30IN(75CM) USP0(M3.5) NON NDL LP
VS3540E	VICRYL RAP UD 30IN(75CM) USP1(M4) NON NDL LP
W9909	VICRYL RAP UD 18IN(45CM) USP4-0(M1.5) S/A SC-1
W9910	VICRYL RAP UD 18IN(45CM) USP5-0(M1) S/A PS-4C PRM
W9911	VICRYL RAP UD 18IN(45CM) USP4-0(M1.5) S/A PS-4C PRM
W9913	VICRYL RAP UD 18IN(45CM) USP6-0(M0.7) S/A P-1 PRM
W9914	VICRYL RAP VIO 12IN(30CM) USP7-0(M0.5) S/A TG140-8
W9915	VICRYL RAP UD 18IN(45CM) USP5-0(M1) S/A P-1 PRM
W9916	VICRYL RAP VIO 12IN(30CM) USP8-0(M0.4) S/A BV-1
W9918	VICRYL RAP UD 30IN(75CM) USP4-0(M1.5) S/A PC-3 PRM
W9919	VICRYL RAP UD 30IN(75CM) USP3-0(M2) S/A PC-3 PRM
W9922	VICRYL RAP UD 30IN(75CM) USP4-0(M1.5) S/A PS-2 PRM
W9923	VICRYL RAP UD 30IN(75CM) USP3-0(M2) S/A PS-2 PRM
W9924	VICRYL RAP UD 30IN(75CM) USP4-0(M1.5) S/A FS-3
W9925	VICRYL RAP UD 30IN(75CM) USP3-0(M2) S/A FS-3
W9926	VICRYL RAP UD 18IN(45CM) USP4-0(M1.5) S/A PS-22 CONV
W9927	VICRYL RAP UD 18IN(45CM) USP3-0(M2) S/A PS-22 CONV

W9928	VICRYL RAP UD 30IN(75CM) USP4-0(M1.5) S/A UV-17
W9929	VICRYL RAP UD 30IN(75CM) USP3-0(M2) S/A UX-25 PRM
W9930	VICRYL RAP UD 30IN(75CM) USP4-0(M1.5) S/A FS-2
W9931	VICRYL RAP UD 30IN(75CM) USP3-0(M2) S/A FS-2
W9932	VICRYL RAP UD 30IN(75CM) USP3-0(M2) S/A PS PRM
W9933	VICRYL RAP UD 30IN(75CM) USP2-0(M3) S/A PS PRM
W9935	VICRYL RAP UD 18IN(45CM) USP3-0(M2) S/A X-1 CONV
W9937	VICRYL RAP UD 30IN(75CM) USP3-0(M2) S/A PSLX PRM
W9938	VICRYL RAP UD 30IN(75CM) USP2-0(M3) S/A PSLX PRM
W9939	VICRYL RAP UD 18IN(45CM) USP4-0(M1.5) S/A KS-45
W9940	VICRYL RAP UD 30IN(75CM) USP3-0(M2) S/A FS
W9941	VICRYL RAP UD 30IN(75CM) USP2-0(M3) S/A FS
W9943	VICRYL RAP UD 30IN(75CM) USP3-0(M2) S/A KS
W9944	VICRYL RAP UD 30IN(75CM) USP2-0(M3) S/A KS
W9945	VICRYL RAP UD 36IN(90CM) USP2-0(M3) S/A V-39
W9948	VICRYL RAP UD 47IN(120CM) USP2-0(M3) S/A V-34
W9961	VICRYL RAP UD 30IN(75CM) USP2-0(M3) S/A FSLX
W9963	VICRYL RAP UD 36IN(90CM) USP0(M3.5) S/A V-34
W9964	VICRYL RAP UD 36IN(90CM) USP1(M4) S/A V-34
W9969	VICRYL RAP UD 30IN(75CM) USP5-0(M1) S/A RB-1
W9970	VICRYL RAP UD 30IN(75CM) USP4-0(M1.5) S/A RB-1