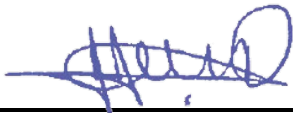


English									
 LEONARDO DA VINCILAAN 15 BE-1831 DIEGEM - Belgium									
EU DECLARATION OF CONFORMITY									
Manufacturer's Name	Johnson & Johnson International								
Manufacturer's Address	c/o European Logistics Centre Leonardo Da Vincilaan 15 BE-1831 Diegem Belgium								
Manufacturer's Single Registration Number (SRN)	BE-MF-000008018								
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 border="1"> <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>0705031a012094L</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	0705031a012094L		
Basic UDI-DI Device Name	Basic UDI-DI Device Model	Basic UDI-DI							
VICRYL RAPIDE (Polyglactin 910) Synthetic Absorbable Suture	Vicryl Rapide	0705031a012094L							
Common Specifications	Common Specifications have not been issued.								
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: EU Technical Documentation Assessment Certificate Number MDR 730044, 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 729796, 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	06-FEB-2023
Name/Title	Valerie Smith Beyer, Director, Regulatory Affairs		
Signature		Date	07-FEB-2023
Name/Title	Veronica Ysunza, Manager, Quality Assurance		
	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

Johnson & Johnson International

EU DECLARATION OF CONFORMITY

Manufacturer's Name	Johnson & Johnson International
Technical Documentation Number	100853329

Suture Characteristics	Range
Suture Material (Absorbable/Non-Absorbable)	Absorbable
Suture Gauge Size	0.4 – 4.0 (Metric)
Suture Length	45 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	Johnson & Johnson International
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
18510G	VICRYL RAP UD 18IN(45CM) USP4-0(M1.5) S/A J-1
MPVR4930H	VICRYL RAP UD 18IN(45CM) USP5-0(M1) S/A P-3 PRM MP
MPVR4940H	VICRYL RAP UD 18IN(45CM) USP4-0(M1.5) S/A P-3 PRM MP
MPVR4960H	VICRYL RAP UD 18IN(45CM) USP4-0(M1.5) S/A PS-2 PRM MP
MPVR4970H	VICRYL RAP UD 18IN(45CM) USP3-0(M2) S/A PS-2 PRM MP
MPVR6830H	VICRYL RAP UD 18IN(45CM) USP3-0(M2) S/A PS-1 PRM MP
MPVR9360H	VICRYL RAP UD 27IN(70CM) USP3-0(M2) S/A PS-1 PRM MP
MPVR9380H	VICRYL RAP UD 27IN(70CM) USP2-0(M3) S/A PS-1 PRM MP
OA1674G	VICRYL RAP UD 27IN(70CM) USP3-0(M2) S/A V-5

OB1674G	VICRYL RAP UD 27IN(70CM) USP3-0(M2) S/A V-7
OB1674H	VICRYL RAP UD 27IN(70CM) USP3-0(M2) S/A V-7
PG1674H	VICRYL RAP UD 27IN(70CM) USP2-0(M3) S/A MH PLUS
PN1695H	VICRYL RAP UD 36IN(90CM) USP0(M3.5) S/A CTX PLUS
TC1696H	VICRYL RAP UD 36IN(90CM) USP1(M4) S/A MO-5
V1002H	VICRYL RAP UD 36IN(90CM) USP2-0(M3) S/A V-7
V2130H	VICRYL RAP UD 27IN(70CM) USP5-0(M1) S/A RB-1 PLUS
V2140G	VICRYL RAP UD 27IN(70CM) USP4-0(M1.5) S/A RB-1 PLUS
V2150G	VICRYL RAP UD 27IN(70CM) USP3-0(M2) S/A RB-1 PLUS
V2150H	VICRYL RAP UD 27IN(70CM) USP3-0(M2) S/A RB-1 PLUS
V2180G	VICRYL RAP UD 27IN(70CM) USP4-0(M1.5) S/A SH-1 PLUS
V2180H	VICRYL RAP UD 27IN(70CM) USP4-0(M1.5) S/A SH-1 PLUS
V2190G	VICRYL RAP UD 27IN(70CM) USP3-0(M2) S/A SH-1 PLUS
V2190H	VICRYL RAP UD 27IN(70CM) USP3-0(M2) S/A SH-1 PLUS
V2910H	VICRYL RAP UD 18IN(45CM) USP5-0(M1) S/A FS-2
V2912G	VICRYL RAP UD 18IN(45CM) USP4-0(M1.5) S/A DA VB
V2920G	VICRYL RAP UD 45CM USP4-0(M1.5) S/A FS-2
V2920H	VICRYL RAP UD 18IN(45CM) USP4-0(M1.5) S/A FS-2
V2930G	VICRYL RAP UD 18IN(45CM) USP3-0(M2) S/A FS-2
V2930H	VICRYL RAP UD 18IN(45CM) USP3-0(M2) S/A FS-2
V4150H	VICRYL RAP UD 27IN(70CM) USP4-0(M1.5) S/A SH PLUS
V4160H	VICRYL RAP UD 27IN(70CM) USP3-0(M2) S/A SH PLUS
V4170H	VICRYL RAP UD 27IN(70CM) USP2-0(M3) S/A SH PLUS
V4420H	VICRYL RAP UD 27IN(70CM) USP3-0(M2) S/A FS-1
V4421H	VICRYL RAP UD 18IN(45CM) USP3-0(M2) S/A FS-1
V4430H	VICRYL RAP UD 27IN(70CM) USP2-0(M3) S/A FS-1
V4431H	VICRYL RAP UD 18IN(45CM) USP2-0(M3) S/A FS-1
V4550H	VICRYL RAP UD 18IN(45CM) USP4-0(M1.5) S/A J-1
V4721H	VICRYL RAP UD 36IN(90CM) USP2-0(M3) S/A CP-1
V4731H	VICRYL RAP UD 36IN(90CM) USP0(M3.5) S/A CP-1

V4851H	VICRYL RAP UD 36IN(90CM) USP0(M3.5) S/A CP
V4861H	VICRYL RAP UD 36IN(90CM) USP1(M4) S/A CP
V4930H	VICRYL RAP UD 18IN(45CM) USP5-0(M1) S/A P-3 PRM
V4940H	VICRYL RAP UD 18IN(45CM) USP4-0(M1.5) S/A P-3 PRM
V4960H	VICRYL RAP UD 18IN(45CM) USP4-0(M1.5) S/A PS-2S PRM
V4961H	VICRYL RAP UD 45CM USP4-0(M1.5) S/A PS-2 VB
V4971H	VICRYL RAP UD 18IN(45CM) USP3-0(M2) S/A PS-2 VB
V5170H	VICRYL RAP UD 36IN(90CM) USP2-0(M3) S/A V-34
V5180H	VICRYL RAP UD 36IN(90CM) USP0(M3.5) S/A V-34
V5190H	VICRYL RAP UD 36IN(90CM) USP1(M4) S/A V-34
V55H	VICRYL RAP UD 27IN(70CM) USP2-0(M3) S/A CT-2 PLUS
V56H	VICRYL RAP UD 27IN(70CM) USP0(M3.5) S/A CT-2 PLUS
V57H	VICRYL RAP UD 27IN(70CM) USP1(M4) S/A CT-2 PLUS
V6191H	VICRYL RAP UD 36IN(90CM) USP0(M3.5) S/A V-37
V62H	VICRYL RAP UD 27IN(70CM) USP2-0(M3) S/A SH-1 PLUS
V66H	VICRYL RAP UD 27IN(70CM) USP0(M3.5) S/A SH PLUS
V6840H	VICRYL RAP UD 18IN(45CM) USP2-0(M3) S/A PS-1 PRM
V7190H	VICRYL RAP UD 36IN(90CM) USP1(M4) S/A V-39
V7191H	VICRYL RAP UD 36IN(90CM) USP0(M3.5) S/A V-40
V76H	VICRYL RAP UD 18IN(45CM) USP3-0(M2) S/A J-1
V7902H	VICRYL RAP UD 18IN(45CM) USP3-0(M2) S/A X-1
V81H	VICRYL RAP UD 18IN(45CM) USP2-0(M3) S/A X-1
V8643E	VICRYL RAP UD 3X18IN(45CM) USP4-0(M1.5) NON NDL
V8644E	VICRYL RAP UD 3X18IN(45CM) USP3-0(M2) NON NDL
V8645E	VICRYL RAP UD 3X18IN(45CM) USP2-0(M3) NON NDL
V8653E	VICRYL RAP UD 2X27IN(70CM) USP2-0(M3) NON NDL
V8654E	VICRYL RAP UD 2X27IN(70CM) USP0(M3.5) NON NDL
V8655H	VICRYL RAP UD 2X27IN(70CM) USP1(M4) NON NDL
V8978E	VICRYL RAP UD 6X18IN(45CM) USP3-0(M2) NON NDL
V8979E	VICRYL RAP UD 6X18IN(45CM) USP2-0(M3) NON NDL

V8980E	VICRYL RAP UD 6X18IN(45CM) USP0(M3.5) NON NDL
V8981E	VICRYL RAP UD 6X18IN(45CM) USP1(M4) NON NDL
V9380H	VICRYL RAP UD 27IN(70CM) USP2-0(M3) S/A PS-1 PRM
V9450H	VICRYL RAP UD 36IN(90CM) USP2-0(M3) S/A CT-1 PLUS
V9460H	VICRYL RAP UD 36IN(90CM) USP0(M3.5) S/A CT-1 PLUS
V9580H	VICRYL RAP UD 36IN(90CM) USP0(M3.5) S/A CT PLUS
W9006	VICRYL RAP UD 60IN(150CM) USP3-0(M2) NON NDL
W9007	VICRYL RAP UD 60IN(150CM) USP2-0(M3) NON NDL
W9946	VICRYL RAP UD 36IN(90CM) USP2-0(M3) S/A V-37
W9947	VICRYL RAP UD 36IN(90CM) USP0(M3.5) S/A V-39
W9962	VICRYL RAP UD 36IN(90CM) USP2-0(M3) S/A V-34
W9971	VICRYL RAP UD 30IN(75CM) USP4-0(M1.5) S/A SH-1 PLUS
W9974	VICRYL RAP UD 30IN(75CM) USP3-0(M2) S/A SH-1
W9975	VICRYL RAP UD 30IN(75CM) USP2-0(M3) S/A MH-1
W9977	VICRYL RAP UD 36IN(90CM) USP0(M3.5) S/A CT
W9978	VICRYL RAP UD 36IN(90CM) USP2-0(M3) S/A CTX PLUS
W9979	VICRYL RAP UD 36IN(90CM) USP0(M3.5) S/A CTX
X605H	VICRYL RAP UD 36IN(90CM) USP1(M4) S/A CTX PLUS