

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	100696219								
Product and Trade Name (s)	MONOCRYL™ Plus Antibacterial Poliglecaprone – 25 (Monofilament), Sterile Synthetic Absorbable Surgical Suture								
Product Code(s)/Product Range and Description	Refer to Attachment 1 Refer to Attachment 2								
Intended Purpose	MONOCRYL™ Plus Sutures are indicated for use in general soft tissue approximation and/or ligation, but not for use in cardiovascular or neurological tissues or ophthalmic surgery.								
Classification	Class III (Annex VIII, Rule(s) 8 and 14)								
GMDN Code	47362, Polyester suture, bioabsorbable, monofilament, antimicrobial								
EMDN Code	H010101030301 Poliglecaprone and Derivatives with Antibacterial Monofilament with Needle								
Basic UDI-DI	<table border="1" style="width: 100%;"> <tr> <th style="text-align: left;">Basic UDI-DI Device Name</th> <th style="text-align: left;">Basic UDI-DI Device Model</th> <th style="text-align: left;">Basic UDI-DI</th> </tr> <tr> <td>MONOCRYL Plus Antibacterial Poliglecaprone – 25 Monofilament Absorbable Suture</td> <td>MONOCRYL Plus Antibacterial Suture</td> <td>0705031a0071857</td> </tr> </table>			Basic UDI-DI Device Name	Basic UDI-DI Device Model	Basic UDI-DI	MONOCRYL Plus Antibacterial Poliglecaprone – 25 Monofilament Absorbable Suture	MONOCRYL Plus Antibacterial Suture	0705031a0071857
Basic UDI-DI Device Name	Basic UDI-DI Device Model	Basic UDI-DI							
MONOCRYL Plus Antibacterial Poliglecaprone – 25 Monofilament Absorbable Suture	MONOCRYL Plus Antibacterial Suture	0705031a0071857							
Common Specifications	Common Specifications have not been issued.								

English

Johnson & Johnson International

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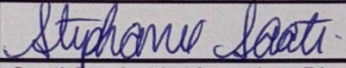
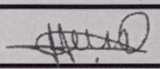
This EU Declaration of Conformity is issued under the sole responsibility of the Manufacturer.

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 730060, 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	10-Nov-2023
Name/Title	Saati Stephanie, Associate Director, Regulatory Affairs		
Signature		Date	10-Nov-2023
Name/Title	Veronica Ysunza, Quality Assurance Manager		
	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

Johnson & Johnson International

LEONARDO DA VINCILAAN 15
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EU DECLARATION OF CONFORMITY

Manufacturer's Name	Johnson & Johnson International
Technical Documentation Number	100696219
Product and Trade names(s)	MONOCRYL™ Plus Antibacterial Poliglecaprone – 25 (Monofilament), Sterile Synthetic Absorbable Surgical Suture
Intended Purpose	MONOCRYL™ Plus Sutures are indicated for use in general soft tissue approximation and/or ligation, but not for use in cardiovascular or neurological tissues or ophthalmic surgery.

Suture Characteristic	Range
Suture Material	Absorbable
Suture Gauge Size	0.7 – 4.0 (Metric)
Suture Length	45 – 90 cm
Suture Dyed/Undyed	Dyed / Undyed
Suture Color (If dyed)	Violet # 2
Suture Coated/Uncoated	Uncoated
Multifilament/Monofilament	Monofilament
Contains Antimicrobials (Yes/No)	Yes
Triclosan Maximum Levels	≤ 2360 µg/m
Accessories to suture type	N/A
Suture Needled/Non-Needled	Needled
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	10 – 60.3 mm
Needle Wire Diameter	0.25 – 1.3mm



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Intended Purpose	MONOCRYL™ Plus Sutures are indicated for use in general soft tissue approximation and/or ligation, but not for use in cardiovascular or neurological tissues or ophthalmic surgery.

Product Code	Product Description
MCP1013H	MONOCRYL PLUS VIO 27IN(70CM) USP5-0(M1) S/A CC-1 MP
MCP1039H	MONOCRYL PLUS UD 27IN(70CM) USP3-0(M2) S/A TS
MCP1086H	MONOCRYL PLUS UD 27IN(70CM) USP2-0(M3) S/A CPA
MCP134H	MONOCRYL PLUS VIO 27IN(70CM) USP6-0(M0.7) S/A RB-4
MCP2023H	MONOCRYL PLUS VIO 27IN(70CM) USP5-0(M1) S/A BB PLUS VB
MCP212H	MONOCRYL PLUS VIO 27IN(70CM) USP6-0(M0.7) S/A RB-1
MCP2131H	MONOCRYL PLUS VIO 27IN(70CM) USP5-0(M1) S/A RB-1 PLUS
MCP215H	MONOCRYL PLUS VIO 27IN(70CM) USP3-0(M2) S/A RB-1 PLUS
MCP218H	MONOCRYL PLUS VIO 27IN(70CM) USP4-0(M1.5) S/A SH-1 PLUS
MCP219G	MONOCRYL PLUS VIO 27IN(70CM) USP3-0(M2) S/A SH-1
MCP220H	MONOCRYL PLUS VIO 27IN(70CM) USP2-0(M3) S/A SH-1 PLUS
MCP227H	MONOCRYL PLUS VIO 27IN(70CM) USP2-0(M3) S/A MH PLUS
MCP228H	MONOCRYL PLUS VIO 27IN(70CM) USP0(M3.5) S/A MH PLUS
MCP229H	MONOCRYL PLUS VIO 27IN(70CM) USP1(M4) S/A MH PLUS
MCP242H	MONOCRYL PLUS VIO 36IN(90CM) USP3-0(M2) S/A SH PLUS
MCP243H	MONOCRYL PLUS VIO 36IN(90CM) USP2-0(M3) S/A SH PLUS
MCP247H	MONOCRYL PLUS VIO 27IN(70CM) USP0(M3.5) S/A MH-1
MCP260H	MONOCRYL PLUS VIO 27IN(70CM) USP0(M3.5) S/A CT-1
MCP2660H	MONOCRYL PLUS UD 27IN(70CM) USP2-0(M3) S/A CP-1
MCP267H	MONOCRYL PLUS UD 27IN(70CM) USP0(M3.5) S/A CP-1
MCP268H	MONOCRYL PLUS UD 27IN(70CM) USP1(M4) S/A CP-1
MCP291H	MONOCRYL PLUS UD 27IN(70CM) USP4-0(M1.5) S/A FS-1
MCP292H	MONOCRYL PLUS UD 18IN(45CM) USP4-0(M1.5) S/A FS-2
MCP293H	MONOCRYL PLUS UD 18IN(45CM) USP3-0(M2) S/A FS-2
MCP295H	MONOCRYL PLUS VIO 27IN(70CM) USP3-0(M2) S/A B-14 PLUS
MCP296H	MONOCRYL PLUS VIO 27IN(70CM) USP2-0(M3) S/A B-16 PLUS
MCP3040H	MONOCRYL PLUS VIO 27IN(70CM) USP4-0(M1.5) S/A RB-1 PLUS VB
MCP3050H	MONOCRYL PLUS VIO 27IN(70CM) USP3-0(M2) S/A RB-1 PLUS VB
MCP3070H	MONOCRYL PLUS VIO 36IN(90CM) USP4-0(M1.5) D/A RB-1 PLUS VB
MCP3100H	MONOCRYL PLUS VIO 27IN(70CM) USP4-0(M1.5) S/A SH-1 PLUS VB
MCP3110H	MONOCRYL PLUS VIO 27IN(70CM) USP3-0(M2) S/A SH-1 PLUS VB
MCP3120H	MONOCRYL PLUS VIO 27IN(70CM) USP2-0(M3) S/A SH-1 PLUS VB
MCP3150H	MONOCRYL PLUS VIO 27IN(70CM) USP4-0(M1.5) S/A SH PLUS VB
MCP3160H	MONOCRYL PLUS VIO 27IN(70CM) USP3-0(M2) S/A SH PLUS VB

Product Code	Product Description
MCP3170H	MONOCRYL PLUS VIO 27IN(70CM) USP2-0(M3) S/A SH PLUS VB
MCP3200H	MONOCRYL PLUS VIO 27IN(70CM) USP3-0(M2) S/A MH-1
MCP3205G	MONOCRYL PLUS UD 27IN(70CM) USP4-0(M1.5) S/A PS-3 PRIME MP
MCP3209G	MONOCRYL PLUS UD 27IN(70CM) USP5-0(M1) S/A FS-2
MCP3212H	MONOCRYL PLUS UD 27IN(70CM) USP4-0(M1.5) S/A PS PRIME MP
MCP3213H	MONOCRYL PLUS UD 27IN(70CM) USP3-0(M2) S/A PS PRIME MP
MCP3218H	MONOCRYL PLUS VIO 27IN(70CM) USP4-0(M1.5) D/A SH-1 PLUS VB
MCP3219H	MONOCRYL PLUS VIO 27IN(70CM) USP3-0(M2) D/A SH-1 PLUS VB
MCP3221G	MONOCRYL PLUS UD 18IN(45CM) USP5-0(M1) S/A FS-3
MCP3224G	MONOCRYL PLUS VIO 18IN(45CM) USP6-0(M0.7) S/A RB-2
MCP3284H	MONOCRYL PLUS VIO 27IN(70CM) USP2-0(M3) S/A MHD-1
MCP3288G	MONOCRYL PLUS VIO 36IN(90CM) USP0(M3.5) S/A CTD
MCP3289G	MONOCRYL PLUS VIO 36IN(90CM) USP1(M4) S/A CTD
MCP3326G	MONOCRYL PLUS UD 27IN(70CM) USP3-0(M2) S/A FS
MCP3327G	MONOCRYL PLUS UD 27IN(70CM) USP2-0(M3) S/A FS
MCP3416H	MONOCRYL PLUS VIO 27IN(70CM) USP3-0(M2) D/A SH PLUS VB
MCP3417H	MONOCRYL PLUS VIO 27IN(70CM) USP2-0(M3) D/A SH PLUS VB
MCP3435G	MONOCRYL PLUS VIO 27IN(70CM) USP4-0(M1.5) S/A RB-1
MCP3440G	MONOCRYL PLUS VIO 27IN(70CM) USP2-0(M3) S/A V-7
MCP3441G	MONOCRYL PLUS VIO 27IN(70CM) USP2-0(M3) S/A MH-1
MCP3488G	MONOCRYL PLUS VIO 27IN(70CM) USP2-0(M3) S/A V-34
MCP3489G	MONOCRYL PLUS VIO 27IN(70CM) USP0(M3.5) S/A V-34
MCP3490G	MONOCRYL PLUS VIO 27IN(70CM) USP1(M4) S/A V-34
MCP3548H	MONOCRYL PLUS VIO 27IN(70CM) USP4-0(M1.5) S/A BB
MCP3600H	MONOCRYL PLUS VIO 27IN(70CM) USP2-0(M3) S/A CP-1
MCP3625H	MONOCRYL PLUS VIO 27IN(70CM) USP3-0(M2) S/A UR-6
MCP3627G	MONOCRYL PLUS VIO 27IN(70CM) USP3-0(M2) D/A SH PLUS
MCP3628G	MONOCRYL PLUS VIO 27IN(70CM) USP2-0(M3) D/A SH PLUS
MCP3649G	MONOCRYL PLUS UD 27IN(70CM) USP4-0(M1.5) S/A KS
MCP3650G	MONOCRYL PLUS UD 27IN(70CM) USP3-0(M2) S/A KS
MCP3651G	MONOCRYL PLUS UD 27IN(70CM) USP2-0(M3) S/A KS
MCP3755G	MONOCRYL PLUS VIO 27IN(70CM) USP1(M4) S/A MH-1
MCP3758H	MONOCRYL PLUS VIO 27IN(70CM) USP0(M3.5) S/A CT
MCP3759G	MONOCRYL PLUS VIO 27IN(70CM) USP1(M4) S/A CT
MCP3770G	MONOCRYL PLUS VIO 36IN(90CM) USP1(M4) S/A CP
MCP388H	MONOCRYL PLUS UD 27IN(70CM) USP6-0(M0.7) S/A C-3
MCP389H	MONOCRYL PLUS UD 27IN(70CM) USP5-0(M1) S/A C-3
MCP390H	MONOCRYL PLUS UD 27IN(70CM) USP4-0(M1.5) S/A C-3
MCP4150H	MONOCRYL PLUS VIO 27IN(70CM) USP4-0(M1.5) S/A SH PLUS
MCP4160H	MONOCRYL PLUS VIO 27IN(70CM) USP3-0(M2) S/A SH PLUS
MCP4170H	MONOCRYL PLUS VIO 27IN(70CM) USP2-0(M3) S/A SH PLUS
MCP418H	MONOCRYL PLUS VIO 27IN(70CM) USP0(M3.5) S/A SH PLUS
MCP4232H	MONOCRYL PLUS VIO 27IN(70CM) USP3-0(M2) S/A CT-2
MCP4236H	MONOCRYL PLUS VIO 27IN(70CM) USP0(M3.5) S/A MO-4
MCP4258H	MONOCRYL PLUS VIO 27IN(70CM) USP3-0(M2) S/A CT-1
MCP4259H	MONOCRYL PLUS VIO 27IN(70CM) USP2-0(M3) S/A CT-1
MCP4260H	MONOCRYL PLUS UD 27IN(70CM) USP4-0(M1.5) S/A PS-2 PRIME MP
MCP4261H	MONOCRYL PLUS VIO 27IN(70CM) USP1(M4) S/A CT-1
MCP4267G	MONOCRYL PLUS VIO 27IN(70CM) USP0(M3.5) S/A CP-1
MCP4269H	MONOCRYL PLUS VIO 27IN(70CM) USP2-0(M3) S/A CT-2
MCP4270H	MONOCRYL PLUS VIO 27IN(70CM) USP0(M3.5) S/A CT-2
MCP4271H	MONOCRYL PLUS UD 27IN(70CM) USP3-0(M2) S/A PS-2 PRIME MP
MCP428H	MONOCRYL PLUS VIO 27IN(70CM) USP3-0(M2) S/A PS-2 PRIME MP
MCP432H	MONOCRYL PLUS VIO 27IN(70CM) USP6-0(M0.7) S/A TF PLUS
MCP4330H	MONOCRYL PLUS VIO 36IN(90CM) USP0(M3.5) S/A CT-2
MCP4331H	MONOCRYL PLUS VIO 36IN(90CM) USP1(M4) S/A CT-2

Product Code	Product Description
MCP4394H	MONOCRYL PLUS UD 27IN(70CM) USP4-0(M1.5) S/A FS-3
MCP4422H	MONOCRYL PLUS UD 27IN(70CM) USP4-0(M1.5) S/A FS-2
MCP4423H	MONOCRYL PLUS UD 27IN(70CM) USP3-0(M2) S/A FS-2
MCP4424H	MONOCRYL PLUS VIO 27IN(70CM) USP3-0(M2) S/A FS-2
MCP442H	MONOCRYL PLUS UD 27IN(70CM) USP3-0(M2) S/A FS-1
MCP443H	MONOCRYL PLUS VIO 27IN(70CM) USP3-0(M2) S/A FS-1
MCP4443H	MONOCRYL PLUS UD 27IN(70CM) USP2-0(M3) S/A FS-1
MCP4444H	MONOCRYL PLUS VIO 27IN(70CM) USP2-0(M3) S/A FS-1
MCP45280H	MONOCRYL PLUS UD 36IN(90CM) USP2-0(M3) D/A SH PLUS VB
MCP457H	MONOCRYL PLUS UD 27IN(70CM) USP4-0(M1.5) S/A J-1
MCP458H	MONOCRYL PLUS UD 27IN(70CM) USP3-0(M2) S/A X-1
MCP459H	MONOCRYL PLUS UD 27IN(70CM) USP2-0(M3) S/A X-1
MCP4664G	MONOCRYL PLUS UD 27IN(70CM) USP2-0(M3) S/A KS
MCP470H	MONOCRYL PLUS VIO 27IN(70CM) USP4-0(M1.5) S/A P-3 PRIME MP
MCP486H	MONOCRYL PLUS UD 36IN(90CM) USP1(M4) S/A CP
MCP489H	MONOCRYL PLUS UD 27IN(70CM) USP6-0(M0.7) S/A P-1 PRIME MP
MCP490H	MONOCRYL PLUS UD 27IN(70CM) USP5-0(M1) S/A P-1 PRIME MP
MCP491H	MONOCRYL PLUS VIO 27IN(70CM) USP5-0(M1) S/A P-3 PRIME MP
MCP492H	MONOCRYL PLUS UD 27IN(70CM) USP6-0(M0.7) S/A P-3 PRIME MP
MCP4930H	MONOCRYL PLUS UD 18IN(45CM) USP5-0(M1) S/A P-3 VB
MCP493H	MONOCRYL PLUS UD 27IN(70CM) USP5-0(M1) S/A P-3 PRIME MP
MCP4940H	MONOCRYL PLUS UD 18IN(45CM) USP4-0(M1.5) S/A P-3 VB
MCP4945H	MONOCRYL PLUS VIO 36IN(90CM) USP2-0(M3) S/A CT-1
MCP4946H	MONOCRYL PLUS VIO 36IN(90CM) USP0(M3.5) S/A CT-1
MCP4947H	MONOCRYL PLUS VIO 36IN(90CM) USP1(M4) S/A CT-1
MCP494H	MONOCRYL PLUS UD 27IN(70CM) USP4-0(M1.5) S/A P-3 PRIME MP
MCP4950G	MONOCRYL PLUS UD 18IN(45CM) USP5-0(M1) S/A DA-1 VB
MCP4957H	MONOCRYL PLUS VIO 36IN(90CM) USP2-0(M3) S/A CT
MCP4958H	MONOCRYL PLUS VIO 36IN(90CM) USP0(M3.5) S/A CT
MCP4959H	MONOCRYL PLUS VIO 36IN(90CM) USP1(M4) S/A CT
MCP495H	MONOCRYL PLUS UD 27IN(70CM) USP5-0(M1) S/A PS-2 PRIME MP
MCP4960H	MONOCRYL PLUS UD 18IN(45CM) USP4-0(M1.5) S/A PS-2 VB
MCP496H	MONOCRYL PLUS UD 18IN(45CM) USP4-0(M1.5) S/A PS-2 PRIME MP
MCP4970H	MONOCRYL PLUS UD 18IN(45CM) USP3-0(M2) S/A PS-2 VB
MCP497H	MONOCRYL PLUS UD 18IN(45CM) USP3-0(M2) S/A PS-2 PRIME MP
MCP498H	MONOCRYL PLUS VIO 27IN(70CM) USP4-0(M1.5) S/A PS-2 PRIME MP
MCP500H	MONOCRYL PLUS UD 27IN(70CM) USP5-0(M1) S/A PS-3 PRIME MP
MCP5218H	MONOCRYL PLUS VIO 36IN(90CM) USP4-0(M1.5) D/A SH-1 PLUS VB
MCP5270H	MONOCRYL PLUS VIO 36IN(90CM) USP3-0(M2) D/A SH PLUS VB
MCP587H	MONOCRYL PLUS UD 27IN(70CM) USP0(M3.5) S/A FSL
MCP589H	MONOCRYL PLUS UD 27IN(70CM) USP2-0(M3) S/A FSL
MCP6050H	MONOCRYL PLUS VIO 27IN(70CM) USP2-0(M3) S/A UR-6
MCP6820H	MONOCRYL PLUS UD 18IN(45CM) USP4-0(M1.5) S/A PS-1 PRIME MP
MCP6830H	MONOCRYL PLUS UD 18IN(45CM) USP3-0(M2) S/A PS-1 VB
MCP683H	MONOCRYL PLUS UD 27IN(70CM) USP3-0(M2) S/A PS-1 PRIME MP
MCP684H	MONOCRYL PLUS UD 27IN(70CM) USP2-0(M3) S/A PS-1 PRIME MP
MCP869H	MONOCRYL PLUS UD 27IN(70CM) USP2-0(M3) S/A CP-2
MCP917H	MONOCRYL PLUS VIO 36IN(90CM) USP2-0(M3) S/A V-34
MCP918H	MONOCRYL PLUS VIO 36IN(90CM) USP0(M3.5) S/A V-34
MCP919H	MONOCRYL PLUS VIO 36IN(90CM) USP1(M4) S/A V-34
MCP925H	MONOCRYL PLUS VIO 27IN(70CM) USP5-0(M1) S/A TF PLUS
MCP9260H	MONOCRYL PLUS VIO 27IN(70CM) USP6-0(M0.7) S/A TF PLUS VB
MCP9350H	MONOCRYL PLUS UD 27IN(70CM) USP4-0(M1.5) S/A PS-1 PRIME MP
MCP946H	MONOCRYL PLUS UNDYED 36IN(90CM) USP0(M3.5) S/A CT-1