

Johnson & Johnson International

LEONARDO DA VINCI LAAN 15
3000 DIEGEM BELGIUM

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

Product: MONOCRYL™ Plus Antibacterial Poliglecaprone-25 (Monofilament),
Sterile Synthetic Absorbable Surgical Suture

Product Range: See Attachment 1 for Product Range

Classification: Class III (Annex IX, Rule 8 and Rule 13)

GMDN Code: 47362

MDD DD Number: ADAPTIV No. 100220721

EC Class III Device Declaration

We, Johnson & Johnson International, hereby declare the above listed Medical Device complies with Council Directive 93/42/EEC as amended by 2007/47/EC. This declaration of conformity is issued under the sole responsibility of the manufacturer.

EC Design Examination Certificate No. CE 518537, issued by the BSI Group The Netherlands B.V. Notified Body Number 2797, in accordance with Annex II Section 4 of Council Directive 93/42/EEC as amended by 2007/47/EC.

EC Quality System Certificate No. CE 589698, issued by the BSI Group The Netherlands B.V. Notified Body Number 2797, in accordance with Annex II Section 3.2 of Council Directive 93/42/EEC as amended by 2007/47/EC.

Place of Issue: Refer to Manufacturer's Address above

Signature: 

Date: May 20, 2021

Title/Position: Joice Pappan, Manager, Regulatory Affairs

Signature: 

Date: MAY 21, 2021

Title/Position: Veronica Ysunza, Quality Assurance Manager

ATTACHMENT 1

Manufacturer's Name: Johnson & Johnson International
Product: MONOCRYL™ Plus Antibacterial Poliglecaprone-25
(Monofilament), Sterile Synthetic Absorbable Surgical Suture
MDD DD Number: 100220721

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

SUPPLEMENTARY INFORMATION

Supplementary Information to MDD Declaration of Conformity

Supplementary Information to MDD Declaration of Conformity 100255224 | Rev: 16
DoC for Monocryl Plus Antibacterial Suture – Non-significant changes approved after
the 26th May 2021 as per Transitional Provisions of MDR Article 120.3

Manufacturer's Name: Johnson & Johnson International

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The transitional provisions specified in MDR Article 120(3) prohibit manufacturers from issuing new Declaration of Conformities or amending, modifying, supplementing any existing MDD Declaration of Conformity from 26th May 2021.

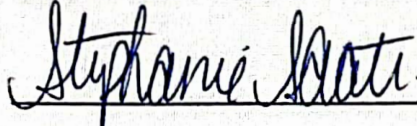
This letter is to confirm that Ethicon Wound Closure and Healing has reviewed and approved the change(s) detailed in the table below. These changes do not represent a change in design or intended purpose under MDR Article 120(3). Declaration of Conformity 100255224 | Rev: 16 DoC for Monocryl Plus Antibacterial Suture remains valid.

Changes Approved:

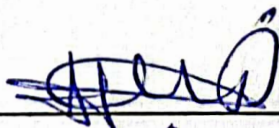
Date	ADAPTIV Reference Number	Certificate Numbers (if applicable for the change)	NB Reference Number (if applicable for the change)	Changes Approved
27-Apr-2022	101014129 100944629	CE 518537	3563109	Updated Section A.4 of Design Dossier to document BSI approval of Triclosan Shelf Life Extension from 5 to 7 years.

Date	ADAPTIV Reference Number	Certificate Numbers (if applicable for the change)	NB Reference Number (if applicable for the change)	Changes Approved
06-Jan-2022	100953227 100853651	CE 518537	3513637	Review of DoC initiated as DEC is renewed –no impact to DoC Updated the following section: A.4 For JJI: Conversion of the SS2 Line at Ethicon, Inc., San Angelo, TX for EO Sterilization of absorbable products utilizing the X Cycle.

Place of Issue: Refer to Manufacturer's Address above

Signature:  Date: 21-Dec-2022
 (wet sign only)

Title/Position: Stephanie Saati, Associate Director, Regulatory Affairs

Signature:  Date: 11-JAN-2023
 (wet sign only)

Title/Position: Veronica Ysunza, Quality Assurance Manager