



DECLARATION OF CONFORMITY

Manufacturer's Name: Ethicon, LLC

Manufacturer's Address: 475C Street
Los Frailes Industrial Park
Suite 401
Guaynabo
Puerto Rico 00969
USA

Authorized Representative: Johnson & Johnson Medical GmbH
Robert-Koch-Strasse 1
Norderstedt
22851
Germany

Product: MONOCRYL™ Poliglecaprone 25 (Monofilament) Sterile
Synthetic Absorbable Surgical Suture

Product Range: See Attachment 1

Classification: Class III (Annex IX, Rule 8)

GMDN Code: 16584

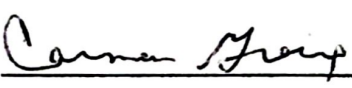
MDD DD Number: ADAPTIV No. 100119315

EC Class III Device Declaration
We, ETHICON, LLC, 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.
This declaration is made on the basis of: EC Design Examination Certificate No. CE 555599, 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 555605, 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: June 29, 2020

Title/Position: Elliott Jang, Associate Director, Regulatory Affairs

Signature:  Date: June 29, 2020

Title/Position: Carmen Gracia, Senior Quality Systems Manager

ATTACHMENT 1

Manufacturer's Name: Ethicon, LLC

Product: MONOCRYL™ Poliglecaprone 25
(Monofilament) Sterile Synthetic Absorbable
Surgical Suture

MDD DD Number: ADAPTIV No. 100119315

Suture Characteristics	Range
Suture Material (Absorbable/Non-Absorbable)	Absorbable
Suture Gauge Size	0.7 – 4.0 (Metric)
Suture Length	45 cm – 150 cm
Suture Dyed/Undyed	Dyed / Undyed
Suture Color (If dyed)	Violet #2
Coated/Uncoated	Uncoated
Multifilament/Monofilament	Monofilament
Contains Antimicrobials (Yes/No)	No
Triclosan Maximum Levels (µg/m)	N/A
Accessories to suture type	N/A
Needled/Non-Needled	Non-Needled/Needled (also available with CONTROL RELEASE™ needles)
Number of Needles per Suture	Single Armed / Double Armed
Needle material	420 SS, 4310 SS and ETHALLOY
Needle coating	Silicone, MULTIPASS and CERBERUS
Needle Shape	Straight / Curve
Needle Color	Black / Silver
Needle Length	8 mm - 70 mm
Needle Wire Diameter	0.25 mm – 1.45 mm

SUPPLEMENTARY INFORMATION

Supplementary Information to MDD Declaration of Conformity

Supplementary Information to MDD Declaration of Conformity 100129668 | Rev: 19
DoC for MONOCRYL Suture – Non-significant changes approved after the 26th May
2021 as per Transitional Provisions of MDR Article 120.3

Manufacturer's Name: Ethicon, LLC

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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.

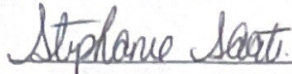
This letter is to confirm that Ethicon Wound Closure and Healing has reviewed and approved the change(s) detailed in the table below. These changes do not represent a change in design or intended purpose under MDR Article 120(3). Declaration of Conformity 100129668 | Rev: 19 DoC for MONOCRYL Suture remains valid.

Changes Approved:

Date	ADAPTIV Reference Number	Certificate Numbers (if applicable for the change)	NB Reference Number (if applicable for the change)	Changes Approved
See Signature	100989486	N/A	N/A	Adding header to the DoC
14-Jun-2022	100953227	CE 555599	3513638	Review of DoC initiated as DEC is renewed –no impact to DoC

Place of Issue: Refer to Manufacturer's Address above

Signature:
(wet sign only)



Date: 17-Oct-2022

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

Signature:
(wet sign only)



Date: 18-Oct-2022

Title/Position: Marjorie Medina, Sr Director Supply Chain Quality EES BIO