



## 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

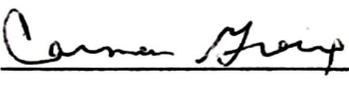
MDD DD Number: ADAPTIV No. 100119315

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: Camen 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

<b>Suture Characteristics</b>	<b>Range</b>
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 26<sup>th</sup> May  
2021 as per Transitional Provisions of MDR Article 120.3

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USA

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 26<sup>th</sup> 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: Stephanie Saati Date: 17-Oct-2022  
(wet sign only)

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

Signature: [Signature] Date: 18-Oct-2022  
(wet sign only)

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