



DECLARATION OF CONFORMITY

Manufacturer's Name: Ethicon, LLC

Manufacturer's Address: 475 C 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: Coated VICRYL™ Plus Antibacterial (Polyglactin 910)
Sterile Synthetic Absorbable Suture

Product Code(s)/ Product Range and Description: Please refer to Attachment 1

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

GMDN Code: 45401

MDD DD Number: 100119364

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 591501, 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:




September 24, 2020

Date:

Title/Position:

Elliott Jang, Associate Director, Regulatory Affairs

Signature:



Date:

Sept. 25, 2020

Title/Position:

Carmen Gracia, Director Quality Make Platform and QS

ATTACHMENT 1

Manufacturer's Name: Ethicon, LLC

Product: Coated VICRYL™ Plus Antibacterial (Polyglactin 910) Sterile
Synthetic Absorbable Suture

MDD DD Number: 100119364

Suture Characteristics	Range
Suture Material (Absorbable/Non-Absorbable)	Absorbable
Suture Gauge Size	1.0 – 5.0 (Metric)
Suture Length	45 cm – 150 cm
Suture Dyed / Undyed	Dyed / Undyed
Suture Color (If dyed)	Violet
Suture Coated / Uncoated (Coating material)	Coated (Copolymer of glycolide and lactide, calcium stearate)
Multifilament / Monofilament	Multifilament
Contains Antimicrobials (Yes/No)	Yes
Triclosan Maximum Levels (µg/m)	≤ 275 µg/m
Accessories to suture type	N/A
Suture 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, ETHALLOY
Needle Coating	Silicone, MULTIPASS, CERBERUS
Needle Shape	Straight / Curve
Needle Length	10 mm – 80 mm
Needle Color	Silver / Black
Needle Wire Diameter	0.305 mm – 1.550 mm

SUPPLEMENTARY INFORMATION

Supplementary Information to MDD Declaration of Conformity

Supplementary Information to MDD Declaration of Conformity 100146796 | Rev: 15
DoC for Coated VICRYL PLUS Suture – Non-significant changes approved after the
26th May 2021 as per Transitional Provisions of MDR Article 120.3

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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.

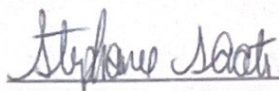
This letter is to confirm that Ethicon Wound Closure and Healing has reviewed and approved the change(s) detailed in the table below. These changes do not represent a change in design or intended purpose under MDR Article 120(3). Declaration of Conformity 100146796 | Rev: 15 DoC for Coated VICRYL PLUS 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	CE 591501	3562092	Adding header to the DoC Updated section A.4 For Ethicon LLC, Guaynabo and JJI: Added Triclosan Shelf Life Extension from 5 to 7 years.
14-Jun-2022	100953227	CE 591501	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