



DECLARATION OF CONFORMITY

Manufacturer's
Name: ETHICON, LLC

Manufacturer's
Address: Highway 183 Km 8.3
San Lorenzo
Puerto Rico
00754
USA

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

Product: ETHIBOND EXCEL™ Polybutylate Coated Polyester Sterile Synthetic
Non Absorbable Surgical Suture

Product Range See Attachment 1 for Product Range

Classification: Class III (Annex IX, Rule 8)

GMDN Code: 13906

MDD DD Number: 100159463

EC Class III Device Declaration

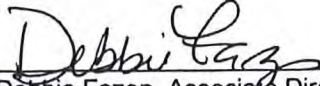
We, ETHICON, LLC, hereby declare the above listed Medical Device complies with Council Directive 93/42/EEC as amended by 2007/47/EC. This declaration of conformity is issued under the sole responsibility of the manufacturer.

This declaration is made on the basis of:
EC Design Examination Certificate No. CE 549316, 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 Certificate No. CE 549314, 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 24, 2021

Title/Position:

Debbie Fazen, Associate Director, Regulatory Affairs

Signature:



Date: 17 JUN 2021

Title/Position:

Adnyl Grovas, Director, Plant Quality Assurance

ATTACHMENT 1

Manufacturer's Name: Ethicon, LLC, San Lorenzo

Product: ETHIBOND EXCEL™ Polybutylate Coated Polyester Sterile Synthetic
Non Absorbable Surgical Suture

MDD DD Number: 100159463

SUTURE CODE RANGE – ETHIBOND EXCEL SUTURE (ETHICON LLC, SAN LORENZO)

Suture Characteristics	Range
Suture Material (Absorbable/Non-Absorbable)	Non-Absorbable
Suture Gauge Size	0.7 – 8.0 (Metric)
Suture Length	20 cm – 180 cm
Suture Dyed/Undyed	Dyed/Undyed
Suture Color (If dyed)	Green
Coated/Uncoated	Coated Only (Polybutylate)
Multifilament/Monofilament	Multifilament
Contains Antimicrobials (Yes/No)	No
Triclosan Maximum Levels (µg/m)	N/A
Accessories to suture type	Retention Tubing, PTFE (polytetrafluoroethylene) Pledgets
Needled/Non-Needled	Needled (Permanent and CONTROL RELEASE) / Non-Needled
Number of Needles per Suture	Single Armed / Double Armed
Needle material	420 SS, 4310 SS, ETHALLOY
Needle coating	Silicone, MULTIPASS, CERBERUS
Needle Color	Silver / Black
Needle Shape	Straight / Curve
Needle Length	8 mm – 254 mm
Needle Wire Diameter	0.279 mm – 1.45 mm