



## 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: 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 555593, 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 555605, issued by the BSI Group The Netherlands 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, 2020

Title/Position:

Elliott Jang, Associate Director, Regulatory Affairs

Signature:



Date:

May 20, 2020

Title/Position:

Carmen Gracia, Sr. Quality Systems Manager

## ATTACHMENT 1

Manufacturer's Name: Ethicon, LLC Guaynabo

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

MDD DD Number: 100159463

### SUTURE CODE RANGE – ETHIBOND EXCEL™ SUTURE (ETHICON, LLC, GUAYNABO)

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 , CERBERUS, MULTIPASS
Needle Color	Silver / Black
Needle Shape	Straight / Curve
Needle Length	8 mm – 254 mm
Needle Wire Diameter	0.279 mm – 1.45 mm

Manufacturer's Name: ETHICON, LLC.

Product: Endosuture System made with ETHIBOND EXCEL™ Suture

MDD DD Number: 100159463

CODE RANGE – ENDOSUTURE SYSTEM MADE WITH ETHIBOND EXCEL™ SUTURE (ETHICON, LLC GUAYNABO)

<b>Endosuture System (ESS) ENDONEEDLE™ Characteristics</b>	<b>Range</b>
Suture Gauge Size	2, 3, 3.5 (Metric)
Suture Length	110 cm
Suture Dyed/Undyed	Dyed (Green)
Needle Material	ETHALLOY, 420 SS, 4310 SS
Needle Coating	Silicone
Needle Shape	Curved
Needle Length	20, 23.8, 24, 26 mm
ESS passer/slider material	High-Density Polyethylene, Black