



LEONARDO DA VINCILAAN 15
BE-1831 DIEGEM - Belgium

DECLARATION OF CONFORMITY

Manufacturer's Name: Johnson & Johnson International

Manufacturer's Address: c/o European Logistics Centre
Leonardo Da Vincilaan 15
BE-1831 Diegem
Belgium

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, Johnson and Johnson International, 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 00819, 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 589698, 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: <u>May 21, 2020</u>
Title/Position:	Elliott Jang, Associate Director, Regulatory Affairs
Signature	 Date <u>MAY 21, 2020</u>
Title/Position	Veronica Ysunza, QA Manager

ATTACHMENT 1

Manufacturer's Name: Johnson & Johnson International
Product: ETHIBOND EXCEL™ Polybutylate Coated Polyester Sterile Synthetic Non Absorbable Surgical Suture
MDD DD Number: 100159463

SUTURE CODE RANGE – ETHIBOND EXCEL™ SUTURE (JOHNSON & JOHNSON INTERNATIONAL)

Suture Characteristics	Range
Suture Material (Absorbable/Non-Absorbable)	Non-Absorbable
Suture Gauge Size	0.5 – 10.0 (Metric)
Suture Length	25 cm – 250 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	N/A
Available presentation	N/A
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, 4310FB SS, ETHALLOY
Needle coating	Silicone, CERBERUS
Needle Shape	Curve
Needle Length	6 mm – 90 mm
Needle Wire Diameter	0.25 mm – 1.45 mm