ETHICON, INC.
a Johnson & Johnson company

DECLARATION OF CONFORMITY

Manufacturer's Name:	ETHICON, INC.
Manufacturer's Address:	PO Box 151 Route 22 West Somerville, NJ 08876-0151 USA
Authorized Representative:	Johnson & Johnson Medical GmbH Robert-Koch-Strasse 1 Norderstedt 22851 Germany
Product:	ETHILON™ (Polyamide 6 or 6,6) Sterile Synthetic Non-Absorbable Surgical Suture
Product Range and Description:	See Attachment 1
Classification:	Class III (Annex IX, Rule 8)
GMDN Code:	38000
MDD DD Number:	ADAPTIV No. 100173897

EC Class III Device Declaration
We, ETHICON INC, 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 basic of: EC Design Certificate No. CE 01589, 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 Full Quality Assurance Certificate No. CE 00384, 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 Manufacture's Address above

Signature: _____ Date: May 5, 2020

Title/Position: Elliott Jang, Associate Director, Regulatory Affairs

ATTACHMENT 1

Manufacturer's Name: ETHICON, INC.

Product: ETHILON™ (Polyamide 6 or 6,6) Sterile Synthetic Non-Absorbable Surgical Suture

MDD DD Number: 100173897

SUTURE CODE RANGE – ETHILON SUTURE (ETHICON, INC)

Suture Characteristics	**Range**
Suture Material (Absorbable/Non-Absorbable)	Non-Absorbable
Suture Gauge Size	0.1 – 5.0 (Metric)
Suture Length	5 cm - 200 cm
Suture Dyed/Undyed	Dyed / Undyed
Suture Color (If dyed)	Black
Suture Coated / Uncoated	Uncoated
Multifilament / Monofilament	Monofilament
Contains Antimicrobials (Yes/No)	No
Triclosan Levels (µg/m)	N/A
Accessories to suture type	Lead Seal and Surgical Bolster, Retention Tubing
Needled / Non-Needled	Needled / Non-Needled
Number of Needles per Suture	Single Armed / Double Armed
Needle Material	420SS, 4310SS, 455 SS, ETHALLOY
Needle Coating	Silicone, CERBERUS, MULTIPASS
Needle Shape	Straight / Curved
Needle Color	Silver / Black
Needle Length	3.5 mm – 90 mm
Needle Wire Diameter	0.051 mm – 1.270 mm