



LEONARDO DA VINCILAAN 15
BE-1831 DIEGEM - Belgium

DECLARATION OF CONFORMITY

Manufacturer's Name: Johnson & Johnson International

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

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

Product Range: See Attachment 1

Classification: Class III (Annex IX, Rule 8)

GMDN Code: 38000 / Nylon Suture, Monofilament

MDD DD Number: 100173897

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 is made on the basis of:

Design Certificate No. CE 01326, issued by the BSI Notified Body Number 0086, in accordance with Annex II, Section 4 of Council Directive 93/42/EEC as amended by 2007/47/EC .

Full Quality Assurance Certificate No. CE 589698, issued by the BSI Notified Body Number 0086, 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:

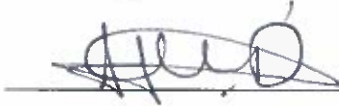


Date: March 23, 2016

Title/Position:

Emily Valerio, Director, Regulatory Affairs

Signature:



Date: March 23, 2016

Title/Position:

Veronica Ysunza, Manager, Quality Assurance

ATTACHMENT 1

Manufacturer's Name: Johnson & Johnson International
Product: ETHILON™ (Polyamide 6 or 6,6) Sterile Synthetic Non-Absorbable Surgical Suture
MDD DD Number: 100173897

SUTURE CODE RANGE – ETHILON (JOHNSON & JOHNSON INTERNATIONAL)

Suture Characteristics	Range
Suture Gauge Size	0.1 – 5.0 Metric
Suture Length	10 cm - 250 cm
Needle Length	3.5 mm – 90 mm
Needle Wire Diameter	0.076 mm – 1.45 mm
Needle Coating	Silicone, MULTIPASS