



LEONARDO DA VINCI LAAN 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: MERSILK™ and PERMA-HAND™ Braided Silk and Virgin Silk Sterile Non-Absorbable Sutures

Product Range: See Attachment 1 for Product Range

Classification: Class III (Annex IX, Rule 8)

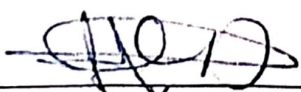
GMDN Code: 13910

MDD DD Number: 100193151

<b>EC Class III Device Declaration</b>
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 01722, issued by 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 System Certificate No. CE 589698, issued by 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: July 06, 2020  
Title/Position: Elliott Jang, Associate Director, Regulatory Affairs

Signature:  Date: JULY 06, 2020  
Title/Position: Veronica Ysunza, Manager, Quality Assurance

**ATTACHMENT 1**

Manufacturer’s Name: Johnson and Johnson International  
 Product: MERSILK™ and PERMA-HAND™ Braided Silk and Virgin Silk Sterile Non-Absorbable Sutures  
 MDD DD Number: 100193151

PRODUCT RANGE – MERSILK™ AND PERMA-HAND™ BRAIDED SILK AND VIRGIN SILK STERILE NON-ABSORBABLE SUTURES (JOHNSON AND JOHNSON INTERNATIONAL)

<b>Suture Characteristics</b>	<b>Range</b>
Suture Material (Absorbable/Non-Absorbable)	Non-Absorbable
Suture Gauge Size	1.0 – 8.0 (Metric)
Suture Length	30 cm – 250 cm
Suture Dyed/Undyed	Dyed / Undyed
Suture Color (If dyed)	Black / Blue
Coated/Uncoated	Coated / Uncoated
Multifilament/Monofilament	Multifilament
Contains Antimicrobials (Yes/No)	No
Accessories to suture type	N/A
Needle material	4310 SS
Needle coating	Silicone, CERBERUS, MULTIPASS
Needle Shape	Straight / Curve
Needled/Non-Needled	Needled (also available with CONTROL RELEASE™ needles) / Non-Needled
Number of Needles per Suture	Single Armed / Double Armed
Needle Length	13 mm – 22 mm
Needle Wire Diameter	0.46 mm – 0.66 mm