

EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices, Annex II Section 4

No. CE 00480
Issued To: **Johnson & Johnson International**
c/o European Logistics Centre
Leonardo Da Vincilaan 15
BE-1831 Diegem
Belgium

In respect of:

PROLENE™ Polypropylene (Monofilament) Sterile, Synthetic Non-absorbable Surgical Suture

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **1995-01-20**

Date: **2019-04-04**

Expiry Date: **2024-04-03**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

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PROLENE™ Polypropylene (Monofilament) Sterile, Synthetic Non-absorbable Surgical Suture from within the following limits are Class III devices, intended for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurosurgical procedures:

Suture Characteristics	Range
Suture Material (Absorbable/Non-Absorbable)	Non-Absorbable
Suture Gauge Size	0.4 - 4.0 (Metric)
Suture Length	45 cm - 90 cm
Suture Dyed/Undyed	Dyed/Undyed
Suture Color (If dyed)	Blue
Coated/Uncoated	Uncoated
Multifilament/Monofilament	Monofilament
Contains Antimicrobials (Yes/No)	No
Triclosan Maximum Levels (µg/m)	N/A
Accessories to suture type	Tubing, Ethisorb Pledgets
Needled/Non-Needled	Needled
Number of Needles per Suture	Single Armed/Double Armed
Needle Material	420 SS, 455 SS, 4310 SS, and ETHALLOY

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Suture Characteristics	Range
Needle Coating	CERBERUS, Silicone, MULTIPASS + Additional Coating of Silicone (Double Dip)
Needle Shape	Curve
Needle Color	Silver/Black
Needle Length	6.5 mm – 90 mm
Needle Wire Diameter	0.152 mm – 1.27 mm

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ENDOLOOP™ Characteristics	Range
Suture Gauge Size	3 (Metric)
Suture Length	90 cm
Suture Dyed / Undyed	Dyed (Blue)
Cannula Specifications	Material: Nylon 11 Length: 38 cm OD: 3.9 mm

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Certificate History

Date	Reference Number	Action
20 January 1995	MD 000736	First Issued.
04 April 1995	MD 000737	Reissue.
22 November 1996		Reissue, new certificate paper.
12 September 1997	MD 000283	Change of company name.
20 January 2000	10010077	Removal of ETHIBOND®, Renewal.
02 September 2002	10041917	Change of company address.
29 May 2003	10050294	Change to sterilisation cycle.
08 July 2003	10051235	Change to 4terilisation ETO cycle.
31 October 2003		Correction to expiration date.
06 February 2004	10054043	Change in packaging (peelable foil) and sterilisation process (Tyvek vent).
29 June 2004	10060179	Change of Packaging.
17 January 2005	10063739	Certificate renewal.

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Date	Reference Number	Action
18 March 2010	10115664	Certificate renewal.
08 August 2012	10135623	Update of wildcard references on certificate supplementary page and packaging and sterilization transfer to Livingston, UK facility for devices packaged in procedure packs.
30 October 2012	10136503	Change of legal manufacturer address.
16 January 2015	10146322	Certificate renewal. Administrative update to supplementary pages.
04 December 2015	10153616	Addition of MULTIPASS + Additional Coating of Silicone (Double Dip) needle coating type Addition of Needle Master File.
18 March 2016	10159048	Change in DuPont™ Tyvek® flash-spinning technology (1073B Transition Tyvek®). Administrative update to scope.
12 January 2017	10153298	Addition of ENDOLOOP. Administrative change to supplementary page.
07 February 2017	10167383	Addition of CERBERUS needle coating type and CERBERUS coating process at Ethicon Cornelia, Georgia. Administrative correction to ENDOLOOP characteristics table.

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Date	Reference Number	Action
10 November 2017	8794404	Addition of Ethicon Athens, GA for the raw material supply of PROLENE Sutures for sizes: 0.5, 0.7, 1, 1.5, 2, 3, 3.5, 4, and 5 (Metric).
05 December 2018	9640463	Change to blackening process for 4310 Stainless Steel VISI-BLACK™ Needles.
02 March 2019	8952310	Traceable to NB 0086.
Current	9687840	Certificate renewal. Administrative update to supplementary page to add the device classification and intended purpose.

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