EC Design-Examination Certificate

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

No. **CE 549330**

Issued To: **Ethicon, LLC**
Highway 183 Km 8.3
San Lorenzo
Puerto Rico
00754
USA

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: **2009-06-17** Date: **2021-04-14** Expiry Date: **2024-04-04**

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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	0.2 – 5.0 (Metric)
Suture Length	7cm – 150 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	Ethilock Fixation Clips (Ethilock locking buttons), PTFE Pledgets
Additional Presentation	HEMO-SEAL needle suture combination
Needled/Non-Needled	Needled (also available with CONTROL RELEASE needles)

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Number of Needles per Suture	Single Armed/Double Armed
Needle material	420 SS, 455 SS, 4310 SS, ETHALLOY and Tungsten/Rhenium
Needle coating	Silicone, EVERPOINT, CERBERUS, MULTIPASS, MULTIPASS + Additional Coating of Silicone (Double-Dip)

Suture Characteristics	**Range**
Needle Shape	Straight/Curve
Needle Color	Silver/Black
Needle Dimensions (Except EVERPOINT™)	
Needle length	3.8 mm – 90 mm
Needle wire diameter	0.076 mm – 1.448 mm
Needle Dimensions (EVERPOINT™)	
Needle length	6.5 mm – 13 mm
Needle wire diameter	0.1524 mm – 0.2667 mm

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Certificate History

Date	Reference Number	Action
17 June 2009	7360606	First issue.
02 March 2011	7653330	Updated scope and supplementary page to include EVERPOINT™ Tungsten Rhenium needles line extension.
16 August 2011	7717739	Review of extension to needle wire diameter for EVERPOINT™ needles to 0.2032mm – 0.2667mm.
30 May 2014	10146323	Certificate renewal. Administrative update of certificate format. Administrative update to scope to align with OEM certificate. Minor administrative typographical corrections. Expiry date realigned with that of the OEM.
20 June 2014	10146197	Addition of 4 EVERPOINT™ 6 mil devices and 2 needle types (BV175-6 [8 mil] and C-1 [10.5 mil]), administrative expansion of wildcard categories for clarity, wildcard ranges narrowed to only include commercialized device ranges.

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Date	Reference Number	Action
14 July 2015	10154943	Addition of thirteen new HEMO-SEAL™ devices utilizing five stainless steel needle codes new to the certificate and four existing 10.5 mil EVERPOINT™ needle codes. Correction of typo (4310FB SS). Changes to labels and IFU.
18 September 2015	10157487	Addition of Suture Characteristic "Additional Presentation" to align with CE 00871.
04 December 2015	10153616	Addition of needle coating type CERBERUS and CERBERUS coating process at Norderstedt, Germany. Addition of Needle Master File.
07 January 2016	10158432	Add global product codes and updates to labelling and IFU (Sat Lorenzo only). Addition of CONTROL RELEASE needle type. Administrative update to scope.
15 July 2016	10158548	Review of implementation of Monofilament Automatic Swaging Machine and Stake Swage. Administrative update to certificate format.
31 August 2016	10162062	Review of pre-sterile testing and addition of alternative sterilisation site and sterilisation cycle.

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Date	Reference Number	Action
27 September 2016	10164644	Conversion of primary packaging for a subset of codes manufactured at Ethicon, LLC (San Lorenzo).
03 November 2016	10167037	Move of some finished goods testing to in-process testing.
07 February 2017	10167383	Addition of CERBERUS coating process at Ethicon Cornelia, Georgia.
19 September 2017	8731944	Addition of global product codes and updates to labeling and IFU (VANTAGE); Removal of Beads and Collars accessory type.
09 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).
28 March 2018	8602688	Addition of sterilization cycle at Livingston, Scotland for E-Packs.
04 July 2018	8332953	Legal Manufacturer transfer of a subset of product codes from Johnson & Johnson International.
05 December 2018	9635244	Change to blackening process for 4310 Stainless Steel VISI-BLACK ™ Needles.
22 February 2019	7781320	Traceable to NB 0086.
5 April 2019	9687844	Certificate renewal. Administrative update to supplementary page to add the device classification and intended purpose.

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Date	Reference Number	Action
5 April 2019	9687844	Certificate renewal. Administrative update to supplementary page to add the device classification and intended purpose.
12 February 2020	9690370	Addition of Multi-slide-based needle manufacturing process for ETHALLOY laser drilled needles at Johnson & Johnson Medical GmbH (Norderstedt, Germany) and Johnson & Johnson do Brasil (São José dos Campos, Brazil) manufacturing facilities. Addition of wire drawing for ETHALLOY stainless steel, 420 SS and 455 SS Johnson & Johnson Medical GmbH (Norderstedt, Germany) and Johnson & Johnson do Brasil (São José dos Campos, Brazil) manufacturing facilities
	9689511 9689542	New global product codes implemented at Ethicon, LLC, San Lorenzo (Project VANTAGE).
01 May 2020	3105447	Addition of manufacture for micro needles (size 2.4 mil to 4.8 mil) at the Johnson & Johnson do Brasil (São José dos Campos, Brasil) manufacturing facility.
Current	3282263	New global product codes implemented at Ethicon, LLC San Lorenzo (Project VANTAGE).

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Supplementary Information to CE 549330 - Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3

Issued to: **Ethicon, LLC**
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Date: 15 November 2021

Changes Approved:

Date	Reference Number	Action
15 November 2021	3261223	Amended - Implementation of two new overwrapping machines at Ethicon, LLC, San Lorenzo. Modification of the format of the cartons and IFUs used at this facility to accommodate the new overwrapping machines.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, Netherlands; Phone : +31 (0)20 346 07 80
Corporate Contact: BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London, W4 4AL, UK. A member of BSI Group of Companies

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Inspiring trust for a more resilient world.

15 November 2021

Ethicon, LLC
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To whom it may concern,

The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) and as per the guidance provided in MDCG 2020-3. The related MDD certificate specified below remains valid until the expiry date specified on the certificate.

Certificate	Directive and Annex	Reference Number	Changes approved
CE 549330	93/42/EEC Annex II Section 4	3261223	Amended - Implementation of two new overwrapping machines at Ethicon, LLC, San Lorenzo. Modification of the format of the cartons and IFUs used at this facility to accommodate the new overwrapping machines.

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,

Gary Slack
Senior Vice President, Medical Devices

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SUSTAINABLE DEVELOPMENT GOALS