EC Design-Examination Certificate

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

No. **CE 549317**

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

In respect of:

ETHILON™ Polyamide 6 or Polyamide 6, 6 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: **2009-06-16** Date: **2021-03-29** Expiry Date: **2024-05-26**

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Ethilon Polyamide 6 or Polyamide 6, 6 Sterile Synthetic Non-Absorbable 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 neurological procedures.

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 / Green
Suture Coated / Uncoated	Uncoated
Multifilament / Monofilament	Monofilament
Contains Antimicrobials (Yes/ No)	No
Triclosan Levels (ug/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	420 SS, 4310 SS, 455 SS, ETHALLOY
Needle Coating	Silicone, CERBERUS, MULTIPASS
Needle Shape	Straight / Curve
Needle Color	Silver/ Black
Needle Length	3.5 mm – 90 mm
Needle Wire Diameter	0.051 mm – 1.270 mm

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Certificate History

Date	Reference Number	Action
16 June 2009	7360602	First issue.
20 August 2012	10135926	Update to new certificate format. Administrative change to supplementary page for clarity.
08 July 2013	10142695	Suture range restricted to current product range and updated to align with OEM CE 01589. Clarification changes. Administrative correction to trademark symbols in scope and administrative addition of supplementary information category 'Suture Needled/Non-needled'.
30 May 2014	10147239	Certificate renewal. Administrative update to supplementary page information. Administrative update to scope. Expiry date realigned with that of the OEM.

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Date	Reference Number	Action
04 December 2015	10153616	Addition of needle coating types CERBERUS & MULTIPASS. Addition of Needle Master File.
19 January 2016	10158430	Add global product codes and updates to labelling and IFU (San Lorenzo and Guaynabo only). Addition of MULTIPASS needle coating type. Addition of Lead Seal and Surgical Bolster. Administrative update to scope.
20 April 2016	10158891	Change in labelling for the removal of special storage conditions and update to the IFU content. Administrative modifications.
06 June 2016	10147241	Review of automated winding machinery, removal of pins in winding machines, change to supplier of the polymer resin used for the suture and use of Zipper III trays. Administrative change to certificate format.
05 July 2016	10162034	New global product codes implemented at San Lorenzo and Ciudad Juarez (VANTAGE 2). Administrative update to supplementary page content.

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Date	Reference Number	Action
26 October 2016	10164519	Addition of Ethicon, Inc. Athens, GA for suture raw material manufacturing (for size USP 3-0, Metric 2 only).
02 December 2016	10166518	New global product codes implemented at San Lorenzo and Ciudad Juarez (VANTAGE 3). Administrative update to supplementary page content.
21 November 2017	8748900	New global product codes implemented at San Lorenzo (Vantage 4). Addition of ETHILON Green. Administrative update to supplementary page content.
22 February 2019	7781320	Traceable to NB 0086.
10 June 2019	9714787	Renewal.

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Date	Reference Number	Action
28 February 2020	9690294	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.
	9689454	New global product codes implemented at San Lorenzo (Project VANTAGE).
03 April 2020	9690712 3105453	Addition of the ETHLION™ Suture sizes USP 2-0 (Metric 3.0) and USP 4-0 (Metric 1.5) manufactured at the Ethicon, Inc. Athens, Georgia manufacturing facility. Addition of manufacture for micro needles (sizes 2.4 mil to 4.8 mil) at the Johnson & Johnson do Brasil (São José dos Campos, Brasil) manufacturing facility.
Current	3249430	Implementation of the Flexible Automatic Swage (FAS) Stake Swage Process at Ethicon, LLC, San Lorenzo, Puerto Rico, USA.

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By Royal Charter

Supplementary Information to CE 549317 - 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.

Inspiring trust for a more resilient world.

15 November 2021

Ethicon, LLC
Highway 183 Km 8.3
San Lorenzo
Puerto Rico
00754
USA

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 549317	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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