EC Design-Examination Certificate

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

No. **CE 549316**

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

In respect of:

ETHIBOND EXCEL™ Polybutylate Coated Polyester 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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ETHIBOND EXCEL™ Polybutylate Coated Polyester Sterile Synthetic Non Absorbable Surgical Suture Needle and Suture combinations 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	0.7 – 8.0 (Metric)
Suture Length	20 cm – 180 cm
Suture Dyed / Undyed	Dyed/Undyed
Suture Color (If dyed)	Green
Coated / Uncoated	Coated Only (Polybutylate)
Multifilament / Monofilament	Multifilament
Contains Antimicrobials (Yes/No)	No
Triclosan Maximum Levels (µg/m)	N/A
Accessories to suture type	Retention Tubing, PTFE (polytetrafluoroethylene) Pledgets

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Suture Characteristics	Range
Needled / Non-Needled	Needled (Permanent and CONTROL RELEASE) / Non-Needled
Number of Needles per Suture	Single Armed/Double Armed
Needle material	420 SS, 4310 SS, ETHALLOY
Needle coating	Silicone, MULTIPASS, CERBERUS
Needle Color	Sliver / Black
Needle Shape	Straight/Curve
Needle Length	8 mm – 254 mm
Needle Wire Diameter	0.279 mm – 1.45 mm

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Certificate History

Date	Reference Number	Action
16 June 2009	7360601	First issue.
30 May 2014	10146902	Certificate renewal. Administrative update to certificate format. Minor administrative typographical corrections. Expiry date realigned with that of the OEM.
30 July 2015	10156176	Certificate renewal and administrative change to scope (from "ETHIBOND™ EXCEL Polyester suture") and wildcard table to clarify / identify existing characteristics and to limit the ranges to those devices currently being manufactured.
04 December 2015	10153616	Addition of Needle Master File.
19 January 2016	10158538	Add global product codes and updates to labelling and IFU (San Lorenzo only). Addition of MULTIPASS needle type. Administrative update to scope.

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Date	Reference Number	Action
23 May 2016	10157379	Change in labelling for the removal of special storage conditions and update to the IFU content. Administrative modifications and change to certificate format.
12 July 2016	10162043	Installation of Flexible Automated Swaging (FAS) Lean Machines with integrated Safety Organizer Tray package winder dial at San Lorenzo, Puerto Rico, USA.
07 February 2017	10167383	Addition of CERBERUS needle coating type and CERBERUS coating process at Ethicon Cornelia, GA.
29 June 2017	8483792	Needle Length range extended to 254 mm.
05 September 2017	8749923	Review of pre-sterile testing and alternative sterilisation site and cycle.
20 September 2017	8750592	Addition of global product codes and update to the IFU (VANTAGE); administrative updates to the supplementary table page.
28 March 2018	8602688	Addition of sterilization cycle at Livingston, Scotland for E-Packs.
15 May 2018	8787285 8892768	Addition of global product codes (Project Vantage).

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Date	Reference Number	Action
26 July 2018	8961186	Addition of global product codes (Project Vantage)
05 December 2018	9635243	Change to blackening process for 4310 Stainless Steel VISI-BLACK™ Needles.
22 February 2019	7781320	Traceable to NB 0086.
11 March 2020	9789238	Certificate renewal
14 May 2020	9690364	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. Administrative update to the supplementary page to include the device classification and intended use per the IFU.
Current	3249430	Line extension to add product codes within the approved ranges. 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 549316 - 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
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00754
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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 549316	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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