

# EC Design-Examination Certificate

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

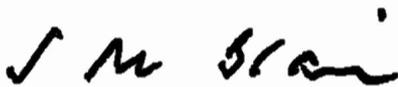
**No.** CE 549326  
**Issued To:** Ethicon, LLC  
Highway 183 Km 8.3  
San Lorenzo  
Puerto Rico  
00754  
USA

In respect of:

**MERSILENE™ and MERSUTURE™ Braided and Monofilament Synthetic Non-absorbable Sutures - Green Dyed and Undyed**

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 0086):



Stewart Brain, Head of Compliance & Risk -  
Medical Devices

First Issued: **2009-11-12**

Date: **2018-06-08**

Expiry Date: **2023-06-15**

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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.

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## Supplementary Information to CE 549326

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### Product: MERSILENE™ and MERSUTURE™ Braided and Monofilament Synthetic Non-absorbable Sutures - Green Dyed and Undyed

Suture Characteristics	Range
Suture Material (Absorbable/Non Absorbable)	Non-Absorbable
Suture Gauge Size	0.1 – 9.0 (Metric)
Suture Length	10cm – 150cm
Suture Dyed/Undyed	Dyed/Undyed
Suture Color (if dyed)	Green
Coated/Uncoated	Uncoated
Multifilament/Monofilament	Multifilament/Monofilament
Contains Antimicrobials (Yes/No)	No
Triclosan Maximum Levels (µg/m)	N/A
Accessories to suture type	N/A
Needled/Non-Needled	Needled (also available with CONTROL RELEASE™ needles) / Non-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	Silicone, CERBERUS, MULTIPASS
Needle Shape	Straight/Curve
Needle Color	Silver / Black
Needle Length	2 mm – 90 mm
Needle Wire Diameter	0.03 mm – 1.80 mm

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## Certificate History

Date	Reference Number	Action
12 November 2009	7449442	First Issue.
31 July 2012	10135924	Update to new certificate format. Administrative change to supplementary pages for clarity only.
30 May 2014	10145719	Certificate renewal. Administrative update to supplementary page. Minor administrative typographical updates. Expiry date realigned with that of the OEM.
10 September 2015	10154879	Change of labelling for storage conditions and other administrative modifications.
04 December 2015	10153616	Addition of Needle Master File.

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Date	Reference Number	Action
18 September 2017	8732034	Addition of global product codes and update to Indication for Use and labelling (VANTAGE). Administrative updates to supplementary page information. Transition from OBL to conformity assessment certificate.  Addition of CERBERUS needle coating.
28 March 2018	8602688	Addition of sterilization cycle at Livingston, Scotland for E-Packs.
Current	8938312	Certificate renewal.

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