

EC Design-Examination Certificate

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

No. CE 555597
Issued To: Ethicon, LLC
475 C Street
Los Frailes Industrial Park
Suite 401
Guaynabo
Puerto Rico
00969
USA

In respect of:

MERSILK™ and PERMA-HAND™ Braided Silk and Virgin Silk Sterile Non-absorbable Sutures

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: **2009-11-13**

Date: **2020-06-28**

Expiry Date: **2024-05-26**

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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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MERSILK™ and PERMA-HAND™ Braided Silk and Virgin Silk Sterile 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.

Description	Dimensions
Suture Material (Absorbable / Non-absorbable)	Non-absorbable
Suture Gauge Size	0.2 – 7.0 (metric)
Suture Lengths	20cm – 180cm
Suture Dyed / Undyed	Dyed/Undyed
Suture Color (if dyed)	Black/Blue
Coated / Uncoated	Coated/Uncoated
Multifilament / Monofilament	Multifilament
Contains Antimicrobials (Yes / No)	No
Accessories to suture type	N/A
Needle Material	420 SS, 455 SS, 4310 SS, ETHALLOY
Needle Coating	Silicone, CERBERUS, MULTIPASS
Needle Shape	Straight / Curve
Needle Color	Silver/ Black

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Description	Dimensions
Needle Lengths	5mm – 90mm
Needle Wire Diameter	0.15mm – 1.27mm
Needled/Non-Needled	Needled (also available with CONTROL RELEASE™ needles)/Non-Needled
Number of Needles per Suture	Single Armed/Double Armed

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Date	Reference Number	Action
13 November 2009	7449443	First Issue.
31 July 2012	10135925	Change of scope from 'MERSILK® and PERMA-HAND® Braided silk' to 'MERSILK®/PERMA-HAND®/SILK Braided silk'. Update to new certificate format. Administrative change to supplementary pages for clarity only.
05 July 2014	10146092	Certificate renewal.
04 December 2015	10153616	Addition of needle coating types CERBERUS & MULTIPASS and CERBERUS coating process at Norderstedt, Germany. Addition of Needle Master File.
27 January 2016	10158160	Change of labelling for the removal of special storage conditions and updates to the IFU content. Administrative updates to supplementary information and scope.
23 February 2016	10161249	Installation Semi Automated Cut and Dispense Machine (SACD) at the Ethicon, Inc. Juarez, Mexico facility.

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Date	Reference Number	Action
25 June 2016	10161649	Certificate renewal. Administrative updates to supplementary page information. Certificate template update for virtual manufacturer. Addition of the word 'sterile' to scope.
07 February 2017	10167383	Addition of CERBERUS coating process at Ethicon Cornelia, Georgia.
28 July 2017	8650602	Transfer of manufacturing for a subset of codes to Ethicon, Inc., Ciudad Juarez.
28 March 2018	8602688	Addition of sterilization cycle at Livingston, Scotland for E-Packs.
26 July 2018	8961197	Addition of global product codes (Project Vantage)
05 December 2018	9635252	Change to blackening process for 4310 Stainless Steel VISI-BLACK™ Needles.
22 February 2019	7781391	Traceable to NB 0086.

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Current	9690485	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.
	3081610	Shelf life reduction from 5 years to 3 years for VIRGIN Blue dyed Silk Suture, Size 8-0.
		Certificate Renewal.
		Administration update to supplementary page to include the device name, classification and intended use.

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