

# EC Design-Examination Certificate

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

**No.****CE 01722**

Issued To:

**Johnson & Johnson International  
c/o European Logistics Centre  
Leonardo Da Vincilaan 15  
BE-1831 Diegem  
Belgium**

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 0086):



Frank Lee, EMEA Compliance & Risk Director

First Issued: **11 July 1996**Date: **25 June 2016**Expiry Date: **10 July 2021**

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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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### **MERSILK™ and PERMA·HAND™ Braided Silk and Virgin Silk Sterile Non-Absorbable Sutures**

<b>Suture Characteristics</b>	<b>Range</b>
Suture Material (Absorbable/Non-Absorbable)	Non-Absorbable
Suture Gauge Size	1.0 - 8.0 (Metric)
Suture Length	30cm - 250cm
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	4310 SS
Needle coating	Silicone, CERBERUS, MULTIPASS
Needle shape	Straight/Curve

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Suture Characteristics	Range
Needled/Non-Needled	Needled (also available with CONTROL RELEASE™ Needles)/Non-Needled
Number of Needles per Suture	Single Armed/Double Armed
Needle Length	13mm – 22mm
Needle Wire Diameter	0.46mm – 0.66mm

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## Certificate History

Date	Reference Number	Action
11 July 1996	MD000146	Certificate first issued.
12 August 1997	MD000279	New certificate format.
12 September 1997	MD000283	Change of company name to Johnson & Johnson International and address.
11 July 2001	10028665	Certificate renewal and inclusion of suture ranges.
30 October 2001	10028665	Correction to report numbers.
02 September 2002	10041917	Change of address.
29 June 2004	10060179	Change of packaging and certificate new format.
04 July 2006	10079988	Certificate renewal.

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Date	Reference Number	Action
07 July 2011	10123652	Certificate renewal.
08 August 2012	10135623	Update of wildcard references on certificate supplementary page and packaging and sterilization transfer to Livingston, UK facility for devices packaged in procedure packs.
06 September 2012	10136503	Change of address. Administrative update to certificate format.
04 December 2015	10153616	Addition of needle coating types CERBERUS & MULTIPASS. 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.
25 June 2016	10161649	Certificate renewal. Administrative updates to supplementary page information. Addition of the word 'sterile' to scope.

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