EC Design-Examination Certificate

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

No. **CE 01305**

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

In respect of:

MONOCRYL™ Poliglecaprone 25 (Monofilament) Sterile Synthetic 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: **1996-05-09** Date: **2020-02-12** Expiry Date: **2024-05-26**

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MONOCRYL™ Poliglecaprone 25 (Monofilament) Sterile Synthetic Absorbable Surgical Suture within the following limits are Class III devices, intended for use in general soft tissue approximation and/or ligation, but not for use in cardiovascular or neurological tissues, microsurgery or ophthalmic surgery:

Suture Characteristics	**Range**
Suture Material (Absorbable/Non-Absorbable)	Absorbable
Suture Gauge Size	0.7 – 4.0 (Metric)
Suture Length	45 - 250 cm
Suture Dyed/Undyed	Dyed/Undyed
Suture Color (If dyed)	Violet #2
Coated/Uncoated	Uncoated
Multifilament/Monofilament	Monofilament
Contains Antimicrobials (Yes/No)	No
Triclosan Maximum Levels (µg/m)	N/A
Accessories to suture type	N/A
Needled/Non-Needled	Non-Needled/ Needled (also available with CONTROL RELEASE™ needles)
Number of Needles per Suture	Single Armed/Double Armed
Needle Material	420 SS, 4310 SS and ETHALLOY

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Suture Characteristics	**Range**
Needle Coating	Silicone, CERBERUS, MULTIPASS
Needle Shape	Straight / Curve
Needle Color	Black / Silver
Needle Length	8 mm – 70 mm
Needle Wire Diameter	0.25mm – 1.45mm

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Certificate History

Date	Reference Number	Action
12 June 1995	MD000005	First Issued Certificate Number 0656. MONOCRYL® POLIGLECAPRONE 25 undyed synthetic absorbable suture.
19 February 1996	MD000092	Extension to scope.
06 March 1996	MD000131	First Issued Certificate Number 1231. MONOCRYL® POLIGLECAPRONE 25 violet dyed synthetic absorbable suture.
09 May 1996	MD000005 MD000092 MD000131 MD000145	Original issue of Certificate CE 01305 bringing together previous two certificates.
10 December 1996		Change of certificate paper.
12 September 1997	MD000283	Change of product and company name.
17 August 1998	MD000283-1	Change of product.
09 May 2001	10026219	Change of product and certificate renewal.
02 September 2002	10041917	Change of address.
29 May 2003	10050294	Change to packaging.
08 July 2003	10051235	Change to sterilization EtO cycle.

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Date	Reference Number	Action
29 June 2004	10060179	Change in packaging.
30 July 2004	10061285	Ethicon GmbH added as an additional manufacturer.
03 May 2006	10078920	Certificate renewal.
19 May 2011	10123380	Modification of scope to align with CE 01075 and more specifically identify the device. Certificate Renewal.
06 September 2012	10136503	Change of address.
05 March 2014	10144913	Administrative update to supplementary page details. Review of Flexible Automated Swage Process at Livingston facility.
07 November 2014	10151494	Certificate renewal. Administrative update to supplementary page.
04 December 2015	10153616	Addition of CERBERUS needle coating type and CERBERUS coating process in Norderstedt, Germany. Addition of Needle Master File.
19 January 2016	10155454	Change of labelling for storage conditions and other administrative modifications.
18 March 2016	10159048	Change in DuPont™ Tyvek® flash-spinning technology (1073B Transition Tyvek®).

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Date	Reference Number	Action
03 August 2016	10162190	Installation of New Packaging Equipment GIFM1 and Ink Change on the Foil Package.
19 September 2016	10162980	Addition of harmonised product codes and update to IFU and labelling at Ciudad Juarez and Kirkton (VANTAGE). Administrative update to certificate scope. Administrative updates to Supplementary Page information.
12 December 2016	10166514	Update to Indication for Use and labelling for global product codes (VANTAGE).
07 February 2017	10167383	Addition CERBERUS coating process at Ethicon Cornelia, GA.
11 August 2017	8716374	Review of BC5 blanking and cartoning machine at San Angelo, TX site.
19 June 2018	8899451	Addition of Athens, GA Suture Raw Material Manufacturing Facility for sizes Metric 1.5 (USP 4-0) and Metric 1 (USP 5-0).
02 March 2019	8952310	Traceable to NB 0086.
30 August 2019	9716908	Certificate Renewal. Scope extension to needle wire diameter to increase the validated range from 0.39mm-1.45mm to 0.25mm-1.45mm. Administrative update to the supplementary page to include the device classification and intended use.

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Date	Reference Number	Action
Current	9690313	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.

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