EC Design-Examination Certificate

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

No. **CE 00585**

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

In respect of:

VICRYL™ (Polyglactin 910) 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):

Albert Roossien, Regulatory Lead

First Issued: **1995-04-11** Date: **2019-03-02** Expiry Date: **2023-11-10**

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VICRYL™ (Polyglactin 910) Sterile Synthetic 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 ophthalmic surgery, peripheral nerve anastomosis and microsurgery for vessels less than 2 mm diameter:

Suture Characteristics	**Range**
Surgical Suture Material (Absorbable/Non-Absorbable)	Absorbable
Surgical Suture Gauge Size	0.2 – 8.0 (Metric)
Surgical Suture Length	5 cm – 2.5 m
Surgical Suture Dyed/Undyed	Dyed/Undyed
Surgical Suture Color (If dyed)	Violet
Coated/Uncoated	Coated (Copolymer of glycolide and L-lactide, calcium stearate)/Uncoated
Multifilament/Monofilament	Multifilament/Monofilament
Contains Antimicrobials (Yes/No)	No
Triclosan Maximum Levels (µg/m)	N/A

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Suture Characteristics	**Range**
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
Needle Coating	Silicone, CERBERUS, MULTIPASS
Needle Shape	Curve/Straight
Needle Color	Silver/Black
Needle Length	3.5 mm – 110 mm
Needle Wire Diameter	0.015 mm – 1.60 mm

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Certificate History

Date	Reference Number	Action
11 April 1995	MD000733	Original issue.
15 May 1996		Re-issue wrong directive on original issue.
10 December 1996		Reissue new certificate paper.
12 September 1997	MD000283	Change of company name.
31 March 2000	10013279	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.
31 October 2003		Correction to Expiration date.
29 June 2004		Change of Packaging.
14 April 2005	10067084	Certificate renewal.
26 July 2010	10116431	Certificate renewal.

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Date	Reference Number	Action
14 July 2011	10123863	Review of GMS supplier change, Drying Process Melt Index Specification Change, Removal of residual testing, Bunte Folder design change, Lacquer formulation change.
06 September 2012	10136503	Change of address.
26 September 2013	10141177	Review of Automated Swaging Process at Livingston facility. Administrative change to supplementary page information.
10 April 2015	10151502	Certificate renewal. Administrative update to scope wording. Administrative update to supplementary page details. Review of revised IFU and labels.
04 December 2015	10153616	Addition of needle coating types CERBERUS & MULTIPASS and CERBERUS coating process at Norderstedt, Germany. Addition of Needle Master File.
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.
26 October 2016	10165053	Addition of Ethicon, Inc. Athens, GA for suture raw material manufacturing for sizes USP 4/0, 2/0,1 (Metric 1.5, 3,4) (56 Denier, Dyed).
31 October 2016	10162977	Addition of harmonised product codes (VANTAGE).
07 February 2017	10167383	Addition of CERBERUS coating process at Ethicon Cornelia, Georgia.
05 May 2017	10169583	Addition of Ethicon, Inc. Athens, GA for suture raw material manufacturing for sizes USP 9-0 (Metric 0.3) (8 Denier, Dyed), USP 6-0 (Metric 0.7) (14 Denier, Un-Dyed), USP 3-0 (Metric 2) (52 Denier, Dyed & Un-Dyed) and USP 4/0, 2/0, 1 (Metric 1.5, 3, 4) (56 Denier, Un-Dyed).

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Date	Reference Number	Action
29 June 2017	8742925	Addition of Ethicon, Inc. Athens, GA for suture raw material manufacturing for sizes USP 8-0 (Metric 0.4) (10 Denier, Dyed), USP 6-0 (Metric 0.7) (14 Denier, Dyed), USP 7-0 (Metric 0.5) (16 Denier, Dyed & Un-Dyed), USP 5-0 (Metric 1) (28 Denier, Dyed), and USP 0 (Metric 3.5) (80 Denier, Dyed & Un-Dyed).
11 August 2017	8716374	Review of BC5 blanking and cartoning machine at San Angelo, TX site.
14 May 2018	8895915	Addition of harmonised product codes and updates to IFU and labelling (VANTAGE).
31 October 2018	8992888	Administrative history section update to reinstate missing review, Ref. 10123863. Administrative update to the supplementary page to include the device classification and intended purpose. Certificate renewal.
06 December 2018	9640468	Change to blackening process for 4310 Stainless Steel VISI-BLACK™ Needles.
Current	8952310	Traceable to NB 0086.

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