By Royal Charter

EC Design-Examination Certificate

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

No. **CE 00584**

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

In respect of:

VICRYL RAPIDE™ (Polyglactin 910) Synthetic Absorbable 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: **1995-04-11** Date: **2020-06-23** Expiry Date: **2024-05-26**

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VICRYL RAPIDE™ (Polyglactin 910) Synthetic Absorbable Suture Needle and Suture combinations from within the following limits are Class III devices, intended for use in soft tissue approximation where only short term wound support is required and where the rapid absorption of the suture would be beneficial. Due to its absorption profile VICRYL RAPIDE™ is useful for skin closure, particularly in pediatric surgery, episiotomies, circumcision and closure of oral mucosa. VICRYL RAPIDE™ is also successfully used in ophthalmic surgery for conjunctival sutures.

Suture Characteristics	**Range**
Suture Material (Absorbable/Non-Absorbable)	Absorbable
Suture Gauge Size	0.4 – 4.0 (Metric)
Suture Length	45 cm – 150 cm
Suture Dyed/Undyed	Dyed/Undyed
Suture Color (If dyed)	Violet
Coated/Uncoated	Coated
Multifilament/Monofilament	Multifilament
Contains Antimicrobials (Yes/No)	No
Triclosan Maximum Levels (µg/m)	N/A
Accessories to suture type	N/A
Needled/Non-Needled	Needled/Non-Needled
Number of Needles per Suture	Single Armed/Double Armed
Needle Material	420 SS, 4310 SS, 4310 FB SS and ETHALLOY

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Suture Characteristics	**Range**
Needle Coating	Silicone, MULTIPASS, CERBERUS
Needle Shape	Straight/Curve
Needle Color	Sliver / Black
Needle Length	5.5 mm – 60 mm
Needle Wire Diameter	0.15 mm – 1.27 mm

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Certificate History

Date	Reference Number	Action
11 April 1995	ME000733	Original issue.
15 May 1996		Reissue, 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.
19 August 2003	10051066	Change in packaging (peelable foil) and sterilization process (Tyvec vent).
10 October 2003	10051025	Add Vicryl Rapide with NVC coating to the product line.
14 April 2005	10067084	Certificate renewal.

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Date	Reference Number	Action
12 July 2010	10116432	Certificate renewal.
22 November 2010	10118975	Review of change in supplier of GMS from Stephen Company to Hallstar Company and change in copolymer drying process.
06 September 2012	10136503	Change of address.
09 April 2015	10153733	Certificate renewal. Updates to IFU/Artwork. Administrative change to scope wording.
04 December 2015	10153616	Addition of Needle Master File.
07 February 2017	10167383	Addition of CERBERUS needle coating type and CERBERUS coating process at Ethicon Cornelia, Georgia.
05 December 2018	9640465	Change to blackening process for 4310 Stainless Steel VISI-BLACK™ Needles.
02 March 2019	8952310	Traceable to NB 0086.
30 March 2020	9789824	Certificate renewal.

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Date	Reference Number	Action
Current	9690189	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.
	3007684	Supplier change for Labyrinth 4Up and 5Up Trays. Increase of the Labyrinth 5up tray height from 2.4 mm to 2.55 mm. Minor dimensional adaptations for the Labyrinth 4up tray.
		Administrative update to the supplementary page to add the device name, classification and intended use.

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