By Royal Charter

EC Design-Examination Certificate

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

No. **CE 569552**

Issued To: **Ethicon, Inc.**
Route 22 West
PO Box 151
Somerville
New Jersey
08876-0151
USA

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 0086):

Frank Lee, EMEA Compliance & Risk Director

First Issued: **09 May 2011** Date: **28 August 2015** Expiry Date: **10 April 2020**

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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, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 845 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A member of BSI Group of Companies.

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VICRYL RAPIDE™ Suture

Suture Characteristics	**Range**
Suture Material (Absorbable/Non-Absorbable)	Absorbable
Suture Gauge Size	0.4 – 4.0 (Metric)
Suture Length	30 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
Needle Shape	Straight/Curve
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
09 May 2011	10119191	Design examination certificate based off CE 00584 with review of relocation of manufacturing to Johnson & Johnson do Brasil Indústria e Comércio de Produtos para Saúde Ltda. and change to packaging materials, First Issue.
26 April 2012	10132905	Administrative update of supplementary page to new format. Review of new folder designs (Universal and Universal Ophthalmic). Change in manufacturing location from J&J Medical GmbH to J&J do Brasil for winding, drying and sterilization processes.
09 April 2015	10153731	Certificate renewal. Updates to IFU/Artwork. Administrative update to certificate format. Administrative change to scope wording. Administrative change to address format.
28 August 2015	10155459	Review for extension the upper limit of the validated Cobalt-60 radiation dose range.

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