By Royal Charter

EC Design-Examination Certificate

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

No. **CE 575366**

Issued To: **Ethicon, LLC**
475 C Street
Los Frailes Industrial Park
Suite 401
Guaynabo
Puerto Rico
00969
USA

In respect of:

ETHICON SECURESTRAP™ Family of Products

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: **06 July 2011** Date: **26 April 2016** Expiry Date: **05 July 2021**

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Description	Product Code	Laparoscopic Port Size (Min.)	Insertable Strap Length	Overall Strap Length	Strap Count per Device	Pack Size
ETHICON SECURESTRAP™ Absorbable Strap Fixation Device	STRAP12	5 mm	6.7 mm	7.3 mm	12	6
	STRAP25	5 mm	6.7 mm	7.3 mm	25	6
	STRAP25R	5 mm	6.7 mm	7.3 mm	25	1

Description	Product Code	Insertable Strap Length	Overall Strap Length	Strap Count per Device	Pack Size
ETHICON SECURESTRAP™ Open Absorbable Strap Fixation Device	OPENSTRAP20	6.7 mm	7.3 mm	20	6
	OPENSTRAP20R	6.7 mm	7.3 mm	20	1
	OPSTRAP20	6.7 mm	7.3 mm	20	6
	OPSTRAP20R	6.7 mm	7.3 mm	20	1

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Certificate History

Date	Reference Number	Action
06 July 2011	7686687	First issue.
19 March 2012	7790839	Addition of STRAP 12 product code. Review of updated label and IFU. Review of updated technical agreement.
20 September 2013	10143475	Update to new certificate format. Administrative Correction to Strap Size from 5mm to 7.3mm.
08 January 2014	10144704	Updated description of devices on certificate (no device change) and updated IFU to emphasize known risks of improper use. Removal of '5mm' from scope.
03 March 2014	10145388	Addition of 2 SecureStrap Open Device codes.
14 May 2014	8134678	Administrative addition of OPSTRAP20 and OPSTRAP20R product codes.
19 December 2015	10159748	Review of design change to SecureStrap Open Device cannula cap and packaging system.

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Date	Reference Number	Action
26 April 2016	10159985	Certificate renewal. Administrative change to certificate format. Review of secondary seal machine and addition of rib to left handle.

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