EC Design-Examination Certificate

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

No. **CE 555593**

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

In respect of:

ETHIBOND EXCEL™ Polybutylate Coated Polyester Sterile Synthetic Non 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: **2009-11-13** Date: **2020-05-14** Expiry Date: **2024-05-26**

...making excellence a habit.™

EC Design-Examination Certificate

Supplementary Information to CE 555593

Issued To:

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

ETHIBOND EXCEL™ Polybutylate Coated Polyester Sterile Synthetic Non 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 cardiovascular, ophthalmic and neurological procedures

Suture Characteristics	**Range**
Suture Material (Absorbable / Non-Absorbable)	Non-Absorbable
Suture Gauge Size	0.7 – 8.0 (Metric)
Suture Length	20 cm – 180 cm
Suture Dyed / Undyed	Dyed/Undyed
Suture Color (If dyed)	Green
Coated / Uncoated	Coated Only (Polybutylate)
Multifilament / Monofilament	Multifilament
Contains Antimicrobials (Yes/No)	No
Triclosan Maximum Levels (µg/m)	N/A
Accessories to suture type	Retention Tubing, PTFE (polytetrafluoroethylene) Pledgets

First Issued: **2009-11-13** Date: **2020-05-14** Expiry Date: **2024-05-26**

EC Design-Examination Certificate

Supplementary Information to CE 555593

Issued To:

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

Suture Characteristics	**Range**
Needled / Non-Needled	Needled (Permanent and CONTROL RELEASE) / Non-Needled
Number of Needles per Suture	Single Armed/Double Armed
Needle Material	420 SS, 4310 SS, ETHALLOY
Needle Coating	Silicone, CERBERUS, MULTIPASS
Needle Color	Sliver / Black
Needle Shape	Straight/Curve
Needle Length	8 mm – 254 mm
Needle Wire Diameter	0.279 mm – 1.45 mm

First Issued: **2009-11-13** Date: **2020-05-14** Expiry Date: **2024-05-26**

...making excellence a habit.™

EC Design-Examination Certificate

Supplementary Information to CE 555593

Issued To:

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

Endosuture System (ESS) ENDONEEDLE™ Characteristics	**Range**
Suture Gauge Size	2, 3, 3.5 (Metric)
Suture Length	110 cm
Suture Dyed / Undyed	Dyed (Green)
Needle material	ETHALLOY, 420 SS, 4310 SS
Needle coating	Silicone
Needle Shape	Curved
Needle Length	20, 23.8, 24, 26 mm
ESS passer / slider material	High-Density Polyethylene, Black

First Issued: **2009-11-13** Date: **2020-05-14** Expiry Date: **2024-05-26**

...making excellence a habit.™

EC Design-Examination Certificate

Supplementary Information to CE 555593

Issued To:

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

Certificate History

Date	Reference Number	Action
13 November 2009	7449449	First issue.
April 2012	7829754	Update of certificate format.
30 May 2014	10146902	Certificate renewal. Administrative update to certificate format. Minor administrative typographical corrections. Expiry date realigned with that of the OEM.
30 July 2015	10156176	Certificate renewal. Administrative change to scope (from "ETHIBOND™ EXCEL Polyester suture") and wildcard table to clarify / identify existing characteristics and to limit the ranges to those devices currently being manufactured.
04 December 2015	10153616	Addition of needle coating types CERBERUS & MULTIPASS and CERBERUS coating process at Norderstedt, Germany. Addition of Needle Master File.

First Issued: **2009-11-13** Date: **2020-05-14** Expiry Date: **2024-05-26**

EC Design-Examination Certificate

Supplementary Information to CE 555593

Issued To:

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

Date	Reference Number	Action
23 May 2016	10157379	Change in labelling for the removal of special storage conditions and update to the IFU content. Administrative modifications and change to certificate format.
24 August 2016	10162041	New global product codes implemented at Ciudad Juarez (VANTAGE 2). Update to supplementary page table information.
04 October 2016	10166005	Change in supplier and processor for polyester yarn. Administrative changes to scope and supplementary information.
28 October 2016	10162838	Transfer of manufacturing from Johnson & Johnson Medical Norderstedt, Germany and Auneau, France to Ethicon Inc., Juarez, Mexico.
12 December 2016	10153303	Addition of Endosuture System ENDONEEDLE.
07 February 2017	10167383	Addition of CERBERUS coating process at Ethicon Cornelia, Georgia.
29 June 2017	8483792	Needle Length range extended to 254 mm.
05 September 2017	8749859	Review of pre-sterile testing and alternative sterilization site and cycle.

First Issued: **2009-11-13** Date: **2020-05-14** Expiry Date: **2024-05-26**

EC Design-Examination Certificate

Supplementary Information to CE 555593

Issued To:

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

Date	Reference Number	Action
28 March 2018	8602688	Addition of sterilization cycle at Livingston, Scotland for E-Packs.
15 May 2018	8787292	Addition of global product codes (Project Vantage).
05 December 2018	9635258	Change to blackening process for 4310 Stainless Steel VISI-BLACK™ Needles.
22 February 2019	7781391	Traceable to NB 0086.
11 March 2020	9789282	Certificate renewal
Current	9690430	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.
	3098235	New global product codes implemented at Ethicon, LLC, Guaynabo (Project VANTAGE).
		Administrative update to the supplementary page to include the device classification and intended use per the IFU.

First Issued: **2009-11-13** Date: **2020-05-14** Expiry Date: **2024-05-26**

...making excellence a habit.™