

# EC Design-Examination Certificate

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

**No.****CE 01326****Issued To:**

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

**In respect of:**

**ETHILON™ Polyamide 6 or Polyamide 6, 6 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: 1996-07-02****Date: 2019-06-10****Expiry Date: 2024-05-26**

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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, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

# EC Design-Examination Certificate

## Supplementary Information to CE 01326

Issued To:

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**c/o European Logistics Centre**  
**Leonardo Da Vincilaan 15**  
**BE-1831 Diegem**  
**Belgium**

**ETHILON™ Polyamide 6 or Polyamide 6, 6 Sterile Synthetic Non-Absorbable Suture 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	0.2 – 5.0 (Metric)
Suture Length	45 cm - 250 cm
Suture Dyed/Undyed	Dyed/Undyed
Suture Color (If dyed)	Black
Coated/Uncoated	Uncoated
Multifilament/Monofilament	Monofilament
Contains Antimicrobials (Yes/No)	No
Triclosan Levels (µg/m)	N/A
Accessories to suture type	Retention Tubing
Needled/Non-Needled	Needled/Non-Needled
Number of Needles per Suture	Single Armed/Double Armed
Needle Material	420 SS, 4310 SS

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Suture Characteristics	Range
Needle Coating	Silicone, MULTIPASS
Needle Shape	Straight/Curve
Needle Color	Silver/Black
Needle Length	8 mm – 75 mm
Needle Wire Diameter	0.20 mm – 1.02 mm

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## Supplementary Information to CE 01326

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**BE-1831 Diegem**  
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## Certificate History

Date	Reference Number	Action
02 July 1996	MD000135	First issue.
22 November 1996	MD000135	New certificate format.
12 September 1997	MD 000285	Change of company name to Johnson & Johnson International, and address.
02 July 2001	10028665	Change of address, inclusion of suture ranges on certificate.
29 June 2004	10060179	Change of packaging, inclusion of suture ranges on certificate, new certificate format.
04 July 2006	10079987	Certificate renewal.
23 June 2011	10123651	Certificate renewal.
06 September 2012	10136503	Change of address. Administrative update to certificate format.
04 December 2015	10153616	Addition of needle coating types Silicone & MULTIPASS. Addition of Needle Master File.

First Issued: **1996-07-02**Date: **2019-06-10**Expiry Date: **2024-05-26**

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Date	Reference Number	Action
20 April 2016	10158891	Change in labelling for the removal of special storage conditions and update to the IFU content. Administrative modifications.
06 June 2016	10147241	Certificate renewal. Review of change to supplier of the polymer resin used for the suture.
26 October 2016	10164519	Addition of Ethicon, Inc. Athens, GA for suture raw material manufacturing (for size USP 3-0, metric 2 only).
02 March 2019	8952310	Traceable to NB 0086.
Current	9714755	Certificate renewal.

First Issued: **1996-07-02**Date: **2019-06-10**Expiry Date: **2024-05-26**

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# EC Certificate - Full Quality Assurance System

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

**No.****CE 589698****Issued To:**

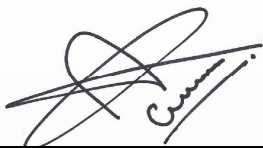
**Johnson & Johnson International  
c/o European Logistics Centre  
Leonardo Da Vincilaan 15  
BE-1831 Diegem  
Belgium**

In respect of:

**Design, development and manufacture of devices as detailed in the Supplementary Information**

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II 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: **2012-09-06**

Date: **2019-03-02**

Expiry Date: **2022-07-07**

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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 approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

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# EC Certificate - Full Quality Assurance System

## Supplementary Information to CE 589698

Issued To:

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

Cords (Absorbable, Sterile)	Surgically Implantable Plugs (Partially Absorbable & Absorbable, Sterile)
Pledgets (Sterile)	Surgical Support Tapes (Absorbable and Non Absorbable, Sterile)
Surgical Bone Wax (Sterile)	Sutures and ligatures (Needled and non-needed, absorbable and non-absorbable, synthetic (including stainless steel) and non-synthetic , medicated and non-medicated) (Sterile)
Surgical Mesh Systems (Non-absorbable, Sterile)	Fixation Clips (Sterile)
Pelvic organ prolapse urogynaecological surgical mesh (sterile)	Surgical Meshes (Partially Absorbable, Absorbable and Non-Absorbable, Sterile)
Surgically Implantable Pins & Plates (Absorbable, Sterile)	

First Issued: **2012-09-06**Date: **2019-03-02**Expiry Date: **2022-07-07**

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# EC Certificate - Full Quality Assurance System

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

## List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 589698**  
Date: **2019-03-02**  
Issued To: **Johnson & Johnson International  
c/o European Logistics Centre  
Leonardo Da Vincilaan 15  
BE-1831 Diegem  
Belgium**

**Subcontractor:****Service(s) supplied**

Ethicon Inc  
1420 Olympic Drive  
Athens  
Georgia  
30601  
USA

**Manufacture**

Ethicon Inc  
3348 Pulliam Street  
San Angelo  
Texas  
76905  
USA

**ETO Sterilization  
Manufacture**

Ethicon Inc  
655 Ethicon Circle  
Cornelia  
Georgia  
30531  
USA

**Manufacture**

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# EC Certificate - Full Quality Assurance System

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### Subcontractor:

### Service(s) supplied

Ethicon Inc  
 Route 22 West  
 Somerville  
 NJ 08876-0151  
 USA

**Design**

Ethicon, Inc.  
 Calle Durango No. 2751  
 Lote Bravo  
 Ciudad Juarez  
 Chihuahua  
 C.P. 32575  
 Mexico

**Manufacture  
 Packaging**

Johnson & Johnson do Brasil Indústria  
 e Comércio de Produtos Para Saúde Ltda.  
 Rod. Presidende Dutra - KM 154  
 São José dos Campos  
 São Paulo  
 12240-908  
 Brasil

**ETO Sterilization  
 Gamma Sterilization  
 Manufacture**

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Belgium**

**Subcontractor:****Service(s) supplied**

Johnson & Johnson MEDICAL GmbH  
Robert-Koch-Strasse 1  
Norderstedt 22851  
Germany

**Design  
ETO Sterilization  
Gamma Sterilization  
Manufacture**

Johnson & Johnson Medical Limited  
Simpson Parkway  
Kirkton Campus  
Livingston  
EH54 7AT  
United Kingdom

**Gamma Sterilization  
Manufacture**

The Secant Group, LLC  
195 O'Neill Drive  
Quakertown  
Pennsylvania  
18951  
USA

**Manufacture**

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# EC Certificate - Full Quality Assurance System

## Certificate History

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Date	Reference Number	Action
06 September 2012	7867743	First issue based on CE 01651.
30 October 2012	7909339	Addition of 'Ethicon Inc, Chihuahua' and 'Ethicon Inc, San Angelo' as significant subcontractors.
14 May 2013	7983862	Correction of expiry date to 7 Jul 2017. Addition of 'Pelvic organ prolapse urogynaecological surgical mesh (sterile)' and 'Sternal fixation system (non-sterile)'.
19 June 2014	8138505	Addition of Partially Absorbable Plugs to Scope and removal of Ethicon S.A.S. France as significant subcontractor due to site closure.
27 January 2015	8254791	Removal of Wound Closure Devices (Sterile) & Sternal Fixation System (Non Sterile) & Addition of Fixation Clips (Sterile) to supplementary table.
17 March 2015	8297184	Addition of Partially Absorbable Surgical Meshes to scope.

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Date	Reference Number	Action
5 July 2017	8713813	<p>Certificate Renewal.</p> <p>Removal of Temporary Cardiac Pacing Wires (Sterile) from scope.</p> <p>Addition of Secant Manufacturing as a significant subcontractor.</p> <p>Addition of Ethicon, Inc. Athens, GA for suture raw material manufacturing.</p> <p>Addition of 'Packaging' as activity for Ethicon Inc., Ciudad Juarez, Mexico.</p> <p>Change of activity to 'ETO Sterilisation' from 'Sterilisation' for Ethicon Inc., San Angelo, Texas.</p> <p>Addition of 'Ethicon, Inc, Georgia' and 'The Secan Group, LLC, Pennsylvania' as significant subcontractors.</p>
5 December 2017	8802715	<p>Addition of significant subcontractor Johnson &amp; Johnson do Brasil Industria for manufacture and sterilization.</p>
Current	8952310	<p>Traceable to NB 0086.</p> <p>Johnson &amp; Johnson do Brasil Indústria e Comércio de Produtos Para Saúde Ltda, São Paulo, 12240-908 from Sterilization to Gamma and ETO Sterilization.</p> <p>Johnson &amp; Johnson MEDICAL GmbH, Norderstedt, 22851 from Sterilization to Gamma and ETO Sterilization.</p> <p>Johnson &amp; Johnson Medical Limited, Livingston, EH54 7AT from Sterilization to Gamma Sterilization.</p>

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