

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 0086):



Pietro Foschi - Strategic Delivery Director

First Issued: **06 September 2012**

Date: **17 March 2015**

Expiry Date: **07 July 2017**

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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.

This certificate was issued electronically and is bound by the conditions of the contract.

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Supplementary Information to CE 589698

Issued To:

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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-needled, absorbable and non-absorbable, synthetic (including stainless steel) and non-synthetic , medicated and non-medicated) (Sterile)
Surgical Mesh Systems (Non-absorbable, Sterile)	Temporary Cardiac Pacing Wires (Sterile)
Pelvic organ prolapse urogynaecological surgical mesh (sterile)	Fixation Clips (Sterile)
Surgical Meshes (Partially Absorbable, Absorbable and Non-Absorbable, Sterile)	
Surgically Implantable Pins & Plates (Absorbable, Sterile)	

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List of Significant Subcontractors

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

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Subcontractor:	Service(s) supplied
Ethicon Inc 3348 Pulliam Street San Angelo Texas 76905 USA	Manufacture Sterilization
Ethicon Inc 655 Ethicon Circle Cornelia Georgia 30531 USA	Manufacture
Ethicon Inc Calle Durango No. 2751 Lote Bravo Ciudad Juarez Chihuahua CP 32575 Mexico	Manufacture

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Subcontractor:	Service(s) supplied
Ethicon Inc Route 22 West Somerville NJ 08876-0151 USA	Design
Johnson & Johnson MEDICAL GmbH Robert-Koch-Strasse 1 Norderstedt 22851 Germany	Design Manufacture Sterilization
Johnson & Johnson Medical Limited Simpson Parkway Kirkton Campus Livingston EH54 7AT United Kingdom	Manufacture Sterilization

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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.