

Certificate

Full Quality Assurance

No. CE 01651



Issued to:

Johnson & Johnson International
c/o European Logistics Centre
Lenneke Marelaan 6
St-Stevens-Woluwe
BE-1932
Belgium

In respect of:

The design, development and manufacture of sterile synthetic absorbable and non-absorbable sutures, ligatures, meshes, temporary wound closure devices; cords, tapes and pledgets; temporary cardiac pacing wires; non-absorbable hemostats, swabs for surgery and ophthalmology; elastic tubing to secure veins, arteries, nerves and uterers, sterile paraffin lubricants, surgical knives and associated accessories

on the basis of our examination under the requirements of Council Directive 93/42/EEC, Annex II, Section 3.2.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Gary Fenton, Global Assurance Director

First Issued: 9 Jul 1997

Date: 4 Jul 2012

Expiration Date: 7 Jul 2017

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Conditions of Approval

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive. 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.

*raising standards worldwide*TM



List of Significant Subcontractors

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

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Subcontractor	Service(s) supplied
Johnson & Johnson MEDICAL GmbH Robert-Koch-Strasse 1 D-22851 Norderstedt Germany	Manufacture Design Sterilization
Ethicon S.A.S. France 63 Rue De la Resistance F-28702 Auneau France	Manufacture
Ethicon Inc 655 Ethicon Circle Cornelia Georgia 30531 USA	Manufacture
Ethicon Inc Route 22 West Somerville NJ 08876-0151 USA	Design

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Subcontractor	Service(s) supplied
Ethicon, a division of Johnson & Johnson Medical Ltd Simpson Parkway Kirkton Campus Livingston EH54 7AT United Kingdom	Manufacture Sterilization

History of Quality Assurance Certificate

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Date	Reference Number	Action
09 July 1997		First Issued.
		Addition of absorbable haemostats and adhesion prevention devices in oxidised regenerated cellulose to scope, Addition of Johnson & Johnson Gargrave.
02 March 1998		Addition of Ethnor, Issy Les Moulineaux and removal of Ethicon Nettlehill Rd
09 March 1999		Name change for both Ethnor sites to Ethicon S.A.S. Addition of Ethicon S.A.S. Garonor.
06 March 2000		Addition of animal derived sutures to scope, Removal of Ethicon, Fountainbridge.
22 March 2002		Removal of Johnson & Johnson Gargrave, Addition of Johnson & Johnson Produtos Profissionais LTDA.
02 September 2002		Change of Address.
07 October 2003		Five yearly renewal, Addition of Beta Gamma for sterilisation, reissued in new format.
20 October 2004		Change to scope to remove animal derived sutures.
05 August 2005		"Absorbable haemostats and adhesion prevention devices in oxidised regenerated cellulose" removed from the scope. Ethicon S.A.S Rue Gamille Des Moulins (France); Ethicon S.A.S Garonor (France); Johnson & Johnson Produtos (Brazil) and BGS Beta-Gamma-Service GmbH & Co KG removed from the list of sub-contractors.

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Date	Reference Number	Action
28 June 2006		"Meshes" added to the scope.
01 November 2006		The scope has changed to include products transferred from another notified body. Ethicon, Inc (Somerville) added to the list of subcontractors. The activities of the subcontractors have been more accurately defined
12 June 2007		Certificate renewal. Ethicon sites at Bankhead Avenue, Edinburgh and Bankhead Crossway, Edinburgh removed from the list of sub-contractors. Inclusion of cord products and non-absorbable hemostats within scope
08 April 2008	7194769	Reissue due to change of name of the subcontractor Ethicon GmbH to Johnson & Johnson MEDICAL GmbH
01 April 2009	7343452	Correction of address of the subcontractor Ethicon, Division of Johnson & Johnson Medical Limited, reissue
30 March 2011	7663278	Addition of Ethicon, Inc. Georgia as significant subcontractor
04 July 2012	7856988	Addition of "Design" to services supplied by significant subcontractor Johnson & Johnson MEDICAL GmbH. Certificate renewal