Manufacturer Evidence

Status : Versioned

Certificate change history

Variation 2 - Updated evidence with Change of notified Body from TUV to BSI. Addition GMDNS codes x 3 & Class IIb added. (Cathie Stoffell, 17/03/2005)

Date received :	16/03/2005
Certificate printed :	No

Variation to Evidence ID: 021126-WEBE-5G8UM2

Notification details

Evidence identifier:	021126-WEBE-5G8UM2
Submission identifier:	DV-2005-0976
Version number:	2
Sponsor's own reference:	Ethicon Sarl #2

Sponsor details

Agent name:	
Sponsor name:	Johnson & Johnson Medical Pty Ltd
Contact details:	[redacted]

Certification details

Manufacturer name:	ETHICON SARL (Switzerland)[32135]
Manufacturer address as on certification:	RUE DU PUITS GODET 20 NEUCHATEL CH-2000 Switzerland S [94903]

Type of product:

○ This certification is to support an application for an in vitro diagnostic medical device (IVD)
● This certification is to support an application for a medical device that is not an in vitro diagnostic medical device (IVD)

Certificate issued under:	Council Directive 93/42/EEC (MDD)
Conformity assessment procedure:	Schedule 3 Part 1 (Annex II)
Source of certification:	BSI Product Services [0086] Lookup
Certificate number:	CE 71259
Certificate issue date: (dd/mm/yyyy)	27/11/2002
Certificate expiry date: (dd/mm/yyyy)	26/11/2007
Certificate re-issue date: (dd/mm/yyyy)	25/02/2005

Restrictions on scope:

Restriction on conformity assessment procedure:
Full Quality Assurance Certificate.
Note: For Class III a Design Examination Certificate must be submitted with the Device Application.

Attached documentation:

Attached documents

Supporting documents:			
#	Document Type	Description	Method

Related Active ARTG Entry Information:	
137081	Johnson & Johnson Medical Pty Ltd - INTERCEED Absorbable Adhesion Barrier - Barrier, absorbable prevention

History

[redacted]

Manufacturer Evidence

Status : Versioned

Certificate change history

Variation 2 - Updated evidence with Change of notified Body from TUV to BSI. Addition GMDNS codes x 3 & Class IIb added. [redacted]
Variation 3 - added two GMDNS codes - 34214, 35280. [redacted]
Variation 4 - addition GMDNS code [45613]. [redacted]

Date received :	19/01/2006
Certificate printed :	No

Variation to Evidence ID: 021126-WEBE-5G8UM2

Notification details

Evidence identifier:	021126-WEBE-5G8UM2
Submission identifier:	DV-2006-7074
Version number:	4
Sponsor's own reference:	Ethicon Sarl #2

Sponsor details

Agent name:	
Sponsor name:	Johnson & Johnson Medical Pty Ltd
Contact details:	[redacted]

Certification details

Manufacturer name:	ETHICON SARL (Switzerland)[32135]
Manufacturer address as on certification:	RUE DU PUITS GODET 20 NEUCHATEL CH-2000 Switzerland S [94903]

Type of product:

○ This certification is to support an application for an in vitro diagnostic medical device (IVD)
● This certification is to support an application for a medical device that is not an in vitro diagnostic medical device (IVD)

Certificate issued under:	Council Directive 93/42/EEC (MDD)
Conformity assessment procedure:	Schedule 3 Part 1 (Annex II)
Source of certification:	BSI Product Services [0086] Lookup
Certificate number:	CE 71259
Certificate issue date: (dd/mm/yyyy)	27/11/2002
Certificate expiry date: (dd/mm/yyyy)	26/11/2007
Certificate re-issue date: (dd/mm/yyyy)	18/04/2005

Restrictions on scope:

Restriction on conformity assessment procedure:
Full Quality Assurance Certificate.

Note: For Class III a Design Examination Certificate must be submitted with the Device Application.

Attached documentation:	
Attached documents	EC Certificate - EC Certif. for Ethicon Sarl Apr 2005.pdf

Supporting documents:			
#	Document Type	Description	Method

Related Active ARTG Entry Information:	
137081	Johnson & Johnson Medical Pty Ltd - INTERCEED Absorbable Adhesion Barrier - Barrier, absorbable prevention

History

[redacted]

Version 4.

EC Certificate

Full Quality Assurance

No. CE 71259

Issued to:

Ethicon SARL
Puits Godet 20
Neuchatel
2000
Switzerland

In respect of:
For the design, development and manufacture of Absorbable Adhesion Prevention Devices composed of Oxidized Regenerated Cellulose, non-absorbable surgical meshes, non-absorbable surgical mesh systems and urinary stress incontinence devices.

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 the British Standards Institution, a Notified Body for the above Directive (Notified Body Number 0086):

[redacted]

BSI Product Services

First Issued: **27 Nov 2002** Date: **18 Apr 2005**

Expiration Date: **26 Nov 2007**

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.

BSI Product Services
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Tel +44 (0)1442 230442 www.bsi-global.com
BSI Group Headquarters: 389 Chiswick High Road, London W4 4AL Tel: (0)208 996 9000

EC Certificate

History of Quality Assurance Certificate

Certificate No: **CE 71259**

Issue Date: **18 April 2005**

Issued to: **Ethicon SARL**

Neuchatel

Date	Action
27 November 2002	First Issue
25 February 2005	Extension to scope and addition of Ethicon Inc (Texas), Ethicon Inc (Puerto Rico), Sterigenics France SA (Rantigny) and Ethicon Inc (Somerville) as sub-contractors.
18 April 2005	Transfer of stress urinary incontinence (TVT) devices and accessories from TÜV to BSI

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EC Certificate

List of Significant Subcontractors

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

Certificate No. **CE 71259**
Date: **18 Apr 2005**
Issued to: **Ethicon SARL**
Neuchatel

Subcontractor	Service(s) supplied
Ethicon Inc 3348 Pullman Street San Angelo TX 76905 USA	Manufacture Sterilization
Ethicon Inc Highway Road 183 Km 8.3 San Lorenzo Puerto Rico 06754 USA	Manufacture
Sterigenics France SA 8 Rue Parmentier 60920 Rantigny France	Sterilization
Ethicon Inc Route 22 West Somerville NJ 08876-0151 USA	Design

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