

# EC Design-Examination Certificate

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

**No.**

**CE 01844**

**Issued To:**

**Ethicon, Inc.  
Route 22 West  
PO Box 151  
Somerville  
New Jersey  
08876-0151  
USA**

In respect of:

**SURGICEL™ FIBRILLAR / TABOTAMP™ FIBRILLAR Absorbable Haemostat  
SURGICEL™ SNoW™ Absorbable Haemostat  
TABOTAMP® SNoW™ Absorbable Haemostat  
TABOTAMP® or TABOTAMP® Original / TABOTAMP® NU-KNIT™ Absorbable Haemostats  
SURGICEL® or SURGICEL® Original / SURGICEL® 2 / SURGICEL® NU-KNIT™ Absorbable  
Haemostats  
SURGICEL® / TABOTAMP® Powder Absorbable Haemostatic Powder**

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 0086):



Stewart Brain, Head of Compliance & Risk -  
Medical Devices

First Issued: **1998-03-05**

Date: **2017-06-14**

Expiry Date: **2018-03-04**

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### SURGICEL™ FIBRILLAR / TABOTAMP™ FIBRILLAR Absorbable Haemostat

Product Code	Size	Description
411961	2.5cm x 5.1cm	SURGICEL™ FIBRILLAR
411962	5.1cm x 10.2cm	SURGICEL™ FIBRILLAR
411963	10.2cm x 10.2cm	SURGICEL™ FIBRILLAR
431961	2.5cm x 5.1cm	TABOTAMP™ FIBRILLAR
431962	5.1cm x 10.2cm	TABOTAMP™ FIBRILLAR
431963	10.2cm x 10.2cm	TABOTAMP™ FIBRILLAR

### SURGICEL™ SNoW™ Absorbable Haemostat / TABOTAMP® SNoW™ Absorbable Haemostat

Product Code	Size	Description
2091	2.5cm x 5.1cm	SURGICEL™ SNoW™
2092	5.1cm x 10.2cm	SURGICEL™ SNoW™
2093	10.2cm x 10.2cm	SURGICEL™ SNoW™
T2091	2.5cm x 5.1cm	TABOTAMP® SNoW™
T2092	5.1cm x 10.2cm	TABOTAMP® SNoW™
T2093	10.2cm x 10.2cm	TABOTAMP® SNoW™

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## **SURGICEL® or SURGICEL® Original Absorbable Haemostats**

Product Code	Size	Description
1901B	5cm x 35cm	SURGICEL® or SURGICEL® Original
1902B	10cm x 20cm	SURGICEL® or SURGICEL® Original
1903B	5cm x 7.5cm	SURGICEL® or SURGICEL® Original
1906B	1.25cm x 5cm	SURGICEL® or SURGICEL® Original
1901E	5cm x 35cm	SURGICEL® or SURGICEL® Original
1902E	10cm x 20cm	SURGICEL® or SURGICEL® Original
1903E	5cm x 7.5cm	SURGICEL® or SURGICEL® Original
1906E	1.25cm x 5cm	SURGICEL® or SURGICEL® Original
1901F	5cm x 35cm	SURGICEL® or SURGICEL® Original
1902F	10cm x 20cm	SURGICEL® or SURGICEL® Original
1903F	5cm x 7.5cm	SURGICEL® or SURGICEL® Original
1906F	1.25cm x 5cm	SURGICEL® or SURGICEL® Original
1901G	5cm x 35cm	SURGICEL® or SURGICEL® Original
1902G	10cm x 20cm	SURGICEL® or SURGICEL® Original

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Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000  
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.  
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### SURGICEL® or SURGICEL® Original Absorbable Haemostats (continued)

Product Code	Size	Description
1903G	5cm x 7.5cm	SURGICEL® or SURGICEL® Original
1901P	5cm x 35cm	SURGICEL® or SURGICEL® Original
1902P	10cm x 20cm	SURGICEL® or SURGICEL® Original
1903P	5cm x 7.5cm	SURGICEL® or SURGICEL® Original
1906P	1.25cm x 5cm	SURGICEL® or SURGICEL® Original
1901EE	5cm x 35cm	SURGICEL® or SURGICEL® Original
1902EE	10cm x 20cm	SURGICEL® or SURGICEL® Original
1903EE	5cm x 7.5cm	SURGICEL® or SURGICEL® Original
1906EE	1.25cm x 5cm	SURGICEL® or SURGICEL® Original
1901GB	5cm x 35cm	SURGICEL® or SURGICEL® Original
1902GB	10cm x 20cm	SURGICEL® or SURGICEL® Original
1903GB	5cm x 7.5cm	SURGICEL® or SURGICEL® Original
1906GB	1.25cm x 5cm	SURGICEL® or SURGICEL® Original
1901KR	5cm x 35cm	SURGICEL® or SURGICEL® Original

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### SURGICEL® or SURGICEL® Original Absorbable Haemostats (continued)

Product Code	Size	Description
1903KR	5cm x 7.5cm	SURGICEL® or SURGICEL® Original
1901SK	5cm x 35cm	SURGICEL® or SURGICEL® Original
1902SK	10cm x 20cm	SURGICEL® or SURGICEL® Original
1903SK	5cm x 7.5cm	SURGICEL® or SURGICEL® Original
1906SK	1.25cm x 5cm	SURGICEL® or SURGICEL® Original
W1911	5cm x 35cm	SURGICEL® or SURGICEL® Original
W1912	10cm x 20cm	SURGICEL® or SURGICEL® Original
W1913T	5cm x 7.5cm	SURGICEL® or SURGICEL® Original
W1915T	1.25cm x 5cm	SURGICEL® or SURGICEL® Original

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### TABOTAMP® or TABOTAMP® Original Absorbable Haemostats

Product Code	Size	Description
1901	5cm x 35cm	TABOTAMP® or TABOTAMP® Original
1902	10cm x 20cm	TABOTAMP® or TABOTAMP® Original
1903	5cm x 7.5cm	TABOTAMP® or TABOTAMP® Original
1906	1.25cm x 5cm	TABOTAMP® or TABOTAMP® Original
1901IT	5cm x 35cm	TABOTAMP® or TABOTAMP® Original
1902IT	10cm x 20cm	TABOTAMP® or TABOTAMP® Original
1903IT	5cm x 7.5cm	TABOTAMP® or TABOTAMP® Original
1906IT	1.25cm x 5cm	TABOTAMP® or TABOTAMP® Original

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## SURGICEL® NU-KNIT™ Absorbable Haemostats

Product Code	Size	Description
1940GB	2.5cm x 2.5cm	SURGICEL® NU-KNIT™
1943GB	7.5cm x 10cm	SURGICEL® NU-KNIT™
1940SK	2.5cm x 2.5cm	SURGICEL® NU-KNIT™
1942SK	5cm x 7.5cm	SURGICEL® NU-KNIT™
1943SK	7.5cm x 10cm	SURGICEL® NU-KNIT™
1940M1	2.5cm x 2.5cm	SURGICEL® NU-KNIT™
1943M1	7.5cm x 10cm	SURGICEL® NU-KNIT™
1946M	15.2cm x 22.9cm	SURGICEL® NU-KNIT™

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### TABOTAMP® NU-KNIT™ Absorbable Haemostats

Product Code	Size	Description
1940IT	2.5cm x 2.5cm	TABOTAMP® NU-KNIT™
1942IT	5cm x 7.5cm	TABOTAMP® NU-KNIT™
1943IT	7.5cm x 10cm	TABOTAMP® NU-KNIT™
1940G	2.5cm x 2.5cm	TABOTAMP® NU-KNIT™
1942G	5cm x 7.5cm	TABOTAMP® NU-KNIT™
1943G	7.5cm x 10cm	TABOTAMP® NU-KNIT™

### SURGICEL® 2 Absorbable Haemostats

Product Code	Size	Description
1941F	2.5cm x 7.5cm	SURGICEL® 2
1943F	7.5cm x 10cm	SURGICEL® 2

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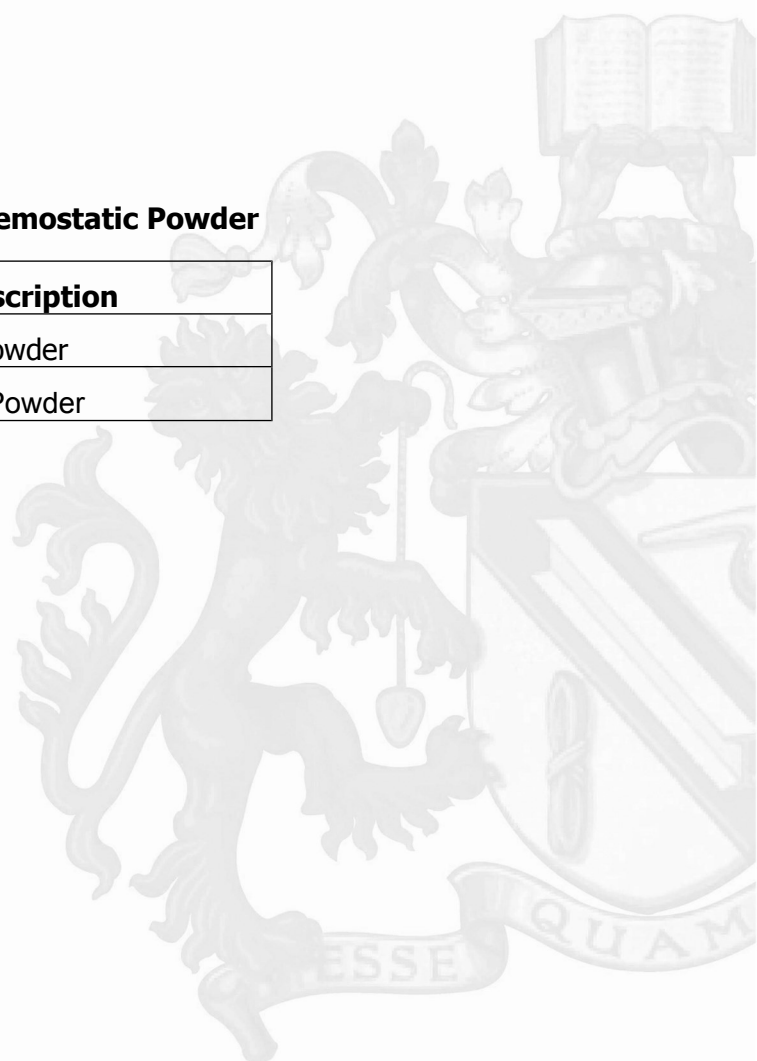
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## **SURGICEL® / TABOTAMP® Powder Absorbable Haemostatic Powder**

Product Code	Size	Description
3023SP	3g ORC Powder	SURGICEL® Powder
3043TP	3g ORC Powder	TABOTAMP® Powder



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## Certificate History

Date	Reference Number	Action
05 March 1998	MD000249	Certificate issue.
13 March 1998		Administrative update to scope to include TAMBOTAMP Fibrallar Absorbable Hemostat trade name (Originally only Surgicel trade name was included).
05 March 2003	10047856	Certificate renewal and new format.
23 July 2003	10047856	Additional subcontractor and change of sterilisation dose.
26 September 2003	10052667	Addition to claims in instruction leaflet.
11 October 2005	10072578	Addition of Steris-Isomedix, Whippany as a subcontract sterilizer.
11 June 2008	10095453	Certificate renewal.
17 March 2009	10103143	Change of EU Representative.
02 March 2011	10121168	Addition of SURGICEL SNoW/TABOTAMP SNoW Absorbable Haemostats.

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Date	Reference Number	Action
28 February 2013	10139818	Administrative update to certificate format. Certificate renewal.
05 February 2014	10143685	Addition of SURGICEL® or SURGICEL® Original / TABOTAMP® or TABOTAMP® Original, SURGICEL® NU-KNIT™ / TABOTAMP® NU-KNIT™ and SURGICEL® 2 Absorbable Haemostats to scope from CE 548159.
27 November 2014	10145707	Addition of automated cutting equipment for Surgicel / Tabotamp SNoW (2091 – 2093 and T2091 – T2093).
18 March 2016	10159048	Change in DuPont™ Tyvek® flash-spinning technology (1073B Transition Tyvek®). Removal of obsolete product codes.
13 July 2016	10163694	Change of manufacturing location at Secant Medical.
20 December 2016	10167444	Review of automated foil equipment.
20 February 2017	10166551	Automation of Slitting Machine (Respooling Machine).
Current	8707112	Addition of SURGICEL® / TABOTAMP® Powder Absorbable Haemostatic Powder.

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