By Royal Charter

EC Design-Examination Certificate

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

No. **CE 549332**

Issued To: **Ethicon, LLC**
Highway 183 Km 8.3
San Lorenzo
Puerto Rico
00754
USA

In respect of:

SURGICEL™ FIBRILLAR / TABOTAMP™ FIBRILLAR Absorbable Haemostat
SURGICEL™ SNoW™ /TABOTAMP® SNoW™ Absorbable Haemostat
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 2797):

Gary E Slack, Senior Vice President - Medical Devices

First Issued: **2009-07-02** Date: **2021-04-14** Expiry Date: **2024-05-26**

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SURGICEL™ FIBRILLAR/TABOTAMP™ FIBRILLAR/ SURGICEL™ SNoW™/TABOTAMP SNoW™ Absorbable Haemostats				
Catalogue Number	**Device Name**	**Model, Type**	**Intended purpose per IFU**	**Classification**
411961	SURGICEL™ FIBRILLAR	2.5 x 5.1cm (1″ x 2″)	SURGICEL™ FIBRILLAR Absorbable Haemostat is used adjunctively in surgical procedures to assist in the control of capillary, venous, and small-arterial haemorrhage when ligation or other conventional methods of control are impractical or ineffective. SURGICEL™ FIBRILLAR Absorbable Haemostat can be cut to size for use in endoscopic procedures	Class III Implant (Annex IX, Rule 8)
411962	SURGICEL™ FIBRILLAR	5.1cm x 10.2cm (2″ x 4″)	Same as above	Class III Implant (Annex IX, Rule 8)
411963	SURGICEL™ FIBRILLAR	10.2cm x 10.2cm (4″ x 4″)	Same as above	Class III Implant (Annex IX, Rule 8)

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SURGICEL™ FIBRILLAR/TABOTAMP™ FIBRILLAR/ SURGICEL™ SNoW™/TABOTAMP SNoW™ Absorbable Haemostats				
Catalogue Number	**Device Name**	**Model, Type**	**Intended purpose per IFU**	**Classification**
431961	TABOTAMP™ FIBRILLAR	2.5 x 5.1cm (1″ x 2″)	TABOTAMP™ FIBRILLAR Absorbable Haemostat is used adjunctively in surgical procedures to assist in the control of capillary, venous, and small-arterial haemorrhage when ligation or other conventional methods of control are impractical or ineffective. TABOTAMP™ FIBRILLAR Absorbable Haemostat can be cut to size for use in endoscopic procedures.	Class III Implant (Annex IX, Rule 8)
431962	TABOTAMP™ FIBRILLAR	5.1cm x 10.2cm (2″ x 4″)	Same as above	Class III Implant (Annex IX, Rule 8)
431963	TABOTAMP™ FIBRILLAR	10.2cm x 10.2cm (4″ x 4″)	Same as above	Class III Implant (Annex IX, Rule 8)

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SURGICEL™ FIBRILLAR/TABOTAMP™ FIBRILLAR/ SURGICEL™ SNoW™/TABOTAMP SNoW™ Absorbable Haemostats				
Catalogue Number	**Device Name**	**Model, Type**	**Intended purpose per IFU**	**Classification**
2091	SURGICEL™ SNoW™	2.5 x 5.1cm (1″ x 2″)	SURGICEL SNoW™ Haemostat is used adjunctively in surgical procedures to assist in the control of capillary, venous, and small-arterial haemorrhage when ligation or other conventional methods of control are impractical or ineffective. SURGICEL SNoW™ Haemostat can be cut to size for use in endoscopic procedures	Class III Implant (Annex IX, Rule 8)
2092	SURGICEL™ SNoW™	5.1cm x 10.2cm (2″ x 4″)	Same as above	Class III Implant (Annex IX, Rule 8)
2093	SURGICEL™ SNoW™	10.2cm x 10.2cm (4″ x 4″)	Same as above	Class III Implant (Annex IX, Rule 8)

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SURGICEL™ FIBRILLAR/TABOTAMP™ FIBRILLAR/ SURGICEL™ SNoW™/TABOTAMP SNoW™ Absorbable Haemostats				
Catalogue Number	**Device Name**	**Model, Type**	**Intended purpose per IFU**	**Classification**
T2091	TABOTAMP® SNoW™	2.5 x 5.1cm (1″ x 2″)	TABOTAMP® SNoW™ Haemostat is used adjunctively in surgical procedures to assist in the control of capillary, venous, and small-arterial haemorrhage when ligation or other conventional methods of control are impractical or ineffective. TABOTAMP® SNoW™ Haemostat can be cut to size for use in endoscopic procedures.	Class III Implant (Annex IX, Rule 8)
T2092	TABOTAMP® SNoW™	5.1cm x 10.2cm (2″ x 4″)	Same as above	Class III Implant (Annex IX, Rule 8)
T2093	TABOTAMP® SNoW™	10.2cm x 10.2cm (4″ x 4″)	Same as above	Class III Implant (Annex IX, Rule 8)

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SURGICEL® / TABOTAMP® Powder Absorbable Haemostatic Powder				
Catalogue Number	**Device Name**	**Model, Type**	**Intended purpose per IFU**	**Classification**
3023SP	SURGICEL® Powder	3g ORC Powder	SURGICEL® Powder (oxidised regenerated cellulose) is used adjunctively in surgical procedures to assist in the control of capillary, venous, and small-arterial haemorrhage when ligation or other conventional methods of control are impractical or ineffective.	Class III Implant (Annex IX, Rule 8)
3043TP	TABOTAMP® Powder	3g ORC Powder	TABOTAMP® Powder (oxidised regenerated cellulose) is used adjunctively in surgical procedures to assist in the control of capillary, venous, and small-arterial haemorrhage when ligation or other conventional methods of control are impractical or ineffective.	Class III Implant (Annex IX, Rule 8)

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Certificate History

Date	Reference Number	Action
02 July 2009	7360895	First issue.
31 March 2011	7662292	OBL updated to include SNoW™ product codes and EU representative information.
17 March 2014	10143688	Update to new certificate format. Alignment of certificate expiry date with expiry date of OEM certificate CE 01844. Certificate renewal.
18 March 2016	10159048	Change in DuPont™ Tyvek® flash-spinning technology (1073B Transition Tyvek®). Administrative update to OEM manufacturer address.
14 June 2017	8707112	Addition of SURGICEL® / TABOTAMP® Powder Absorbable Haemostatic Powder.
03 January 2018	8867956	Review of updated Instructions of Use.
28 February 2018	8887269	Certificate renewal.
22 March 2019	7781320	Traceable to NB 0086.

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Date	Reference Number	Action
08 November 2019	9690371 9698767	SURGICEL™ / TABOTAMP™ Powder bellows applicator white colorant change. SURGICEL™ / TABOTAMP Powder manufacturing sampling plan change. Administrative update to the supplementary page to include supplementary product information.
15 May 2020	3118247	Update to SURGICEL™ /TABOTAMP ™ Powder & Fabric Instructions for Use (IFU). Update to the bacterial nomenclature on the SURGICEL ™ /TABOTAMP ® SNoW™ IFU. Administrative update to supplementary page device tables
Current	3218967	Certificate renewal Correction of device table heading on page 6 to SURGICEL® / TABOTAMP® Powder Absorbable Haemostatic Powder Addition of "™" and "®" to device trade names in certificate history table

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Supplementary Information to CE 549332 - Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3

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Date: 09 March 2022

Changes Approved:

Date	Reference Number	Action
09 March 2022	3511064	Optimization of sampling plan for one finished Good Inspection criteria and five in-coming inspection components.

Inspiring trust for a more resilient world.

09 March 2022

Ethicon, LLC
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To whom it may concern,

The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) and as per the guidance provided in MDCG 2020-3. The related CE 549332 below remains valid until the expiry date specified on the certificate.

Certificate	Directive and Annex	Reference Number	Changes approved
CE 549332	**93/42/EEC Annex II Section 4**	**3511064**	**Optimization of sampling plan for one Finished Good Inspection criteria and five in-coming inspection components.**

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,

Graeme Tunbridge
Senior Vice President, Medical Devices

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