



DECLARATION OF CONFORMITY

Manufacturer's Name: Ethicon LLC

Manufacturer's Address: Highway 183 Km 8.3
San Lorenzo 00754
Puerto Rico
USA

Authorized Representative: Johnson & Johnson Medical GmbH*
Robert-Koch-Strasse 1
Norderstedt
22851
Germany

Product: Surgicel/Tabotamp® Fibrillar Absorbable Haemostat
Surgicel/Tabotamp® SNoW Absorbable Haemostat
Surgicel/Tabotamp® Powder Absorbable Haemostatic Powder

Product Codes and Description: See Attachment 1

Classification: Class III (Annex IX, Rule 8)

GMDN Code: 38771

MDD DD Number: 100096051

EC Class III Device Declaration	
We, Ethicon LLC, hereby declare the above listed Medical Device complies with Council Directive 93/42/EEC as amended by 2007/47/EC. This declaration of conformity is issued under the sole responsibility of the manufacturer.	
This declaration is made on the basis of: EC Design Examination Certificate No.549332, issued by the BSI Group The Netherlands B.V. Notified Body Number 2797, in accordance with Annex II Section 4 of this Council Directive 93/42/EEC as amended by 2007/47/EC.	
EC Quality System Certificate No. 549314, issued by the BSI Group The Netherlands B.V. Notified Body Number 2797, in accordance with Annex II Section 3.2 of this Council Directive 93/42/EEC as amended by 2007/47/EC.	

Place of Issue: Refer to Manufacturer's Address above

Signature:

 Date: 25 MAY 2021

Title/Position:

Joseph Chmielewski, Director, Regulatory Affairs

Signature:

 Date: 25 MAY 2021

Title/Position:

Adnyl Grovas, Plant Quality Assurance Director

ATTACHMENT 1

Manufacturer's Name: Ethicon LLC

Product: Surgicel/Tabotamp® Fibrillar Absorbable Haemostat
Surgicel/Tabotamp® SNoW Absorbable Haemostat
Surgicel/Tabotamp® Powder Absorbable Haemostatic Powder

MDD DD Number: 100096051

List of Product Codes:

Code	Trade Name	Product Description/Size
411961	SURGICEL® Fibrillar	2.5 cm x 5.1 cm
411962	SURGICEL® Fibrillar	5.1 cm x 10.2 cm
411963	SURGICEL® Fibrillar	10.2 cm x 10.2 cm
431961	TABOTAMP® Fibrillar	2.5 cm x 5.1 cm
431962	TABOTAMP® Fibrillar	5.1 cm x 10.2 cm
431963	TABOTAMP® Fibrillar	10.2 cm x 10.2 cm
2091	SURGICEL® SNoW	2.5 cm x 5.1 cm
2092	SURGICEL® SNoW	5.1 cm x 10.2 cm
2093	SURGICEL® SNoW	10.2 cm x 10.2 cm
T2091	TABOTAMP® SNoW	2.5 cm x 5.1 cm
T2092	TABOTAMP® SNoW	5.1 cm x 10.2 cm
T2093	TABOTAMP® SNoW	10.2 cm x 10.2 cm
3023SP	SURGICEL® Powder Absorbable Haemostatic Powder	3 g ORC Powder
3043TP	TABOTAMP® Powder Absorbable Haemostatic Powder	3 g ORC Powder