

DECLARATION OF CONFORMITY
DECLARACION DE CONFORMIDAD / KONFORMITÄTSERKLÄRUNG

MANUFACTURER / Fabricante / Hersteller	B. Braun Surgical, S.A. Ctra. de Terrassa, 121 08191 Rubí (Barcelona), Spain
PRODUCT / Producto / Produkte	OPTILENE MESH ELASTIC (cm) 7.5x15;10x15;15x15;20x30;30x30;30x50;35x10
PRODUCT CODE / Código de producto / Artikelnummer	Detailed information enclosed Información detallada adjunta Detaillierte Informationen beigelegt
CLASS, RULE / Clase, regla / Risikoklasse, Regel (Annex IX MDD)	IIb, 8
CONFORMITY ASSESSMENT ROUTE / Evaluación de la conformidad / Konformitätsbewertungsverfahren nach	Annex II.3 of the COUNCIL DIRECTIVE 93/42/ECC of 14 June 1993 concerning medical devices
NOTIFIED BODY / Organismo Notificado / Benannte Stelle	TÜV Sud Product Service Ridlerstrasse, 65, 80339 München, Germany NB No 0123
START OF CE MARKING / Inicio marca CE / Beginn der CE-Kennzeichnung	16-05-2011
CE Certificate/ Certificado CE / EG Bescheinigung	G1 025701 0090 Rev.01

WE HEREWITH DECLARE UNDER OUR SOLE RESPONSIBILITY, THAT THE ABOVE MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 93/42/EEC FOR MEDICAL DEVICES.

Por la presente nosotros declaramos bajo nuestra responsabilidad, que los productos arriba mencionados cumplen con los requisitos de la Directiva 93/42/EEC de Productos Sanitarios.

Erklären in alleiniger Verantwortung, dass der oben genannte Artikel mit den Anforderungen der Medizinprodukte Richtlinie 93/42/EWG übereinstimmt.

Rubí, 4th April 2022ⁱ

This document is signed electronically

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Reference	Product Name / Description
1064900	OPTILENE MESH ELASTIC 30 X 30 CM
1064910	OPTILENE MESH ELASTIC 15 X 15 CM
1064920	OPTILENE MESH ELASTIC 10 X 15 CM
1064930	OPTILENE MESH ELASTIC 7,5 X 15 CM
1064940	OPTILENE MESH ELASTIC 20X30 CM
1064970	OPTILENE MESH ELASTIC 35X10 CM
1064980	OPTILENE MESH ELASTIC 30X50 CM
1064900UNI	OPTILENE MESH ELASTIC 30 X 30 CM
1064910UNI	OPTILENE MESH ELASTIC 15 X 15 CM
1064920UNI	OPTILENE MESH ELASTIC 10 X 15 CM
1064930UNI	OPTILENE MESH ELASTIC 7,5 X 15 CM
1064940UNI	OPTILENE MESH ELASTIC 20X30CM
1964900	OPTILENE MESH ELASTIC BLUE 30 X 30 CM
1964910	OPTILENE MESH ELASTIC BLUE 15 X 15 CM
1964920	OPTILENE MESH ELASTIC BLUE 10 X 15 CM
1964930	OPTILENE MESH ELASTIC BLUE 7,5 X 15 CM
1964940	OPTILENE MESH ELASTIC BLUE 20X30CM
1964970	OPTILENE MESH ELASTIC BLUE 35X10 CM
1964980	OPTILENE MESH ELASTIC BLUE 30X50 CM
1964900UNI	OPTILENE MESH ELASTIC BLUE 30 X 30 CM
1964910UNI	OPTILENE MESH ELASTIC BLUE 15 X 15 CM
1964920UNI	OPTILENE MESH ELASTIC BLUE 10 X 15 CM
1964930UNI	OPTILENE MESH ELASTIC BLUE 7,5 X 15 CM
1964940UNI	OPTILENE MESH ELASTIC BLUE 20X30CM
1964970UNI	OPTILENE MESH ELASTIC BLUE 35X10 CM
1964980UNI	OPTILENE MESH ELASTIC BLUE 30X50 CM

ⁱ DoC has been signed after 26th of May 2021, due to clause 6.6 of SOP/31/OP/005 (v.10).

Title: DoC Optilene Mesh Elastic Initiator: Maria del Carmen ? Gutierrez

This document is signed electronically in compliance with the B. Braun electronic signature policies and procedures by following persons:

UserName: Ibañez, Heliazar (ibanhees)
Title: SU-RA-ES04 Regulatory Affairs Technician
Date: Tuesday, 05 April 2022, 10:53 W. Europe Daylight Time
Meaning: Document signed as Author

UserName: Orús, Silvia Salut (orussies)
Title: Global Regulatory Affairs Manager CoE CT
Date: Wednesday, 06 April 2022, 15:48 W. Europe Daylight Time
Meaning: Approve Document

UserName: Turón, Pau (turopaes)
Title: VP R&D B. Braun Group (Spain)
Date: Thursday, 07 April 2022, 15:58 W. Europe Daylight Time
Meaning: Approve Document
