

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 SILVER MESH ELASTIC (cm) 7.5x15; 10x15; 15x15; 20x30; 30x30
PRODUCT CODE / Código de producto / Artikelnummer	Detailed information enclosed Información detallada adjunta Detaillierte Informationen beigelegt
CLASS, RULE / Clase, regla / Risikoklasse, Regel (Annex IX MDD)	III, 8 and 13
CONFORMITY ASSESSMENT ROUTE / Evaluación de la conformidad / Konformitätsbewertungsverfahren nach	Annex II.3 and II.4 of the COUNCIL DIRECTIVE 93/42/EEC 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	29-10-2019
CE Certificate/ Certificado CE / EG Bescheinigung	G7 025701 0079 Rev.01 // 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, 25.03.2022ⁱ

This document is signed electronically

DECLARATION OF CONFORMITY
DECLARACION DE CONFORMIDAD / KONFORMITÄTSEKLRUNG

Reference	Product Name / Description
-----------	----------------------------

CODES	DESCRIPTION OPTILENE SILVER MESH ELASTIC
1265250	Optilene Silver Mesh Elastic 7.5x15 cm
1265240	Optilene Silver Mesh Elastic 10x15 cm
1265230	Optilene Silver Mesh Elastic 15x15 cm
1265220	Optilene Silver Mesh Elastic 20x30 cm
1265210	Optilene Silver Mesh Elastic 30x30 cm
1265250UNI	Optilene Silver Mesh Elastic 7.5 X 15 cm
1265240UNI	Optilene Silver Mesh Elastic 10 X 15 cm
1265230UNI	Optilene Silver Mesh Elastic 15 X 15 cm
1265220UNI	Optilene Silver Mesh Elastic 20 X 30 cm
1265210UNI	Optilene Silver Mesh Elastic 30 X 30 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 Silver 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: Pinto, Constanza Maria (pintcoes)
Title: SU-RA-ES04 Regulatory Affairs Technician
Date: Tuesday, 29 March 2022, 11:42 W. Europe Daylight Time
Meaning: Document signed as Author

UserName: Orús, Silvia Salut (orussies)
Title: Global Regulatory Affairs Manager CoE CT
Date: Wednesday, 30 March 2022, 23:33 W. Europe Daylight Time
Meaning: Approve Document

UserName: Turón, Pau (turopaes)
Title: VP R&D B. Braun Group (Spain)
Date: Thursday, 31 March 2022, 17:17 W. Europe Daylight Time
Meaning: Approve Document
