

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 LP (cm) 4.5x10; 5x10; 6x14; 7.5x15; 10x15; 15x15
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

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Reference	Product Name / Description
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CODES	DESCRIPTION OPTILENE SILVER MESH LP
1265360	Optilene Silver Mesh LP HOLE/TAILS 4.5x10 cm
1265350	Optilene Silver Mesh LP 5x10 cm
1265340	Optilene Silver Mesh LP HOLE/TAILS 6x14 cm
1265330	Optilene Silver Mesh LP 7.5x15 cm
1265320	Optilene Silver Mesh LP 10x15 cm
1265310	Optilene Silver Mesh LP 15x15 cm
1265360UNI	Optilene Silver Mesh LP HOLE/TAILS 4.5X10 cm
1265350UNI	Optilene Silver Mesh LP 5 X 10 cm
1265340UNI	Optilene Silver Mesh LP HOLE/TAILS 6X14 cm
1265330UNI	Optilene Silver Mesh LP 7.5 X 15 cm
1265320UNI	Optilene Silver Mesh LP 10 X 15 cm
1265310UNI	Optilene Silver Mesh LP 15 X 15 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 LP 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)
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Date: Thursday, 31 March 2022, 17:15 W. Europe Daylight Time
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