

**DECLARATION OF CONFORMITY**  
**DECLARACION DE CONFORMIDAD / KONFORMITÄTSERKLÄRUNG**

<b>MANUFACTURER /</b> Fabricante / Hersteller	B. Braun Surgical, S.A. Ctra. de Terrassa, 121 08191 Rubí (Barcelona), Spain
<b>PRODUCT /</b> Producto / Produkte	OPTILENE MESH LP (cm)4.5x10;5x10;6x12.5;6x14;6x35;7.5x7.5; 7.5x15;8x35;10x15;10x35;15x15;15x20;20x20
<b>PRODUCT CODE /</b> Código de producto / Artikelnummer	Detailed information enclosed Información detallada adjunta Detaillierte Informationen beigefügt
<b>CLASS, RULE /</b> Clase, regla / Risikoklasse, Regel (Annex IX MDD)	IIb, 8
<b>CONFORMITY ASSESSMENT ROUTE /</b> Evaluación de la conformidad / Konformitätsbewertungsverfahren nach	Annex II.3 of the COUNCIL DIRECTIVE 93/42/ECC of 14 June 1993 concerning medical devices
<b>NOTIFIED BODY /</b> Organismo Notificado / Benannte Stelle	TÜV Sud Product Service Ridlerstrasse, 65, 80339 München, Germany NB No 0123
<b>START OF CE MARKING /</b> Inicio marca CE / Beginn der CE-Kennzeichnung	16-05-2011
<b>CE Certificate/</b> 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, 4<sup>th</sup> April 2022<sup>i</sup>**

This document is signed electronically

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Reference	Product Name / Description
1064705	OPTILENE MESH LP 15 X 15 CM
1064715	OPTILENE MESH LP 7,5 X 15 CM
1064725	OPTILENE MESH LP 10 X 15 CM
1064735	OPTILENE MESH LP 5 X 10 CM
1064755	OPTILENE MESH LP 7,5 X 7,5 CM
1064765	OPTILENE MESH LP HOLE/TAILS 4,5 X 10 CM
1064775	OPTILENE MESH LP HOLE/TAILS 6 X 14 CM
1064825	OPTILENE MESH LP PRESHAPE 4,5 X 10 CM
1064845	OPTILENE MESH LP PRESHAPE 6 X 14 CM
1064855	OPTILENE MESH LP 15 X 20 CM
1064865	OPTILENE MESH LP 6X35CM
1064875	OPTILENE MESH LP 8X35 CM
1064885	OPTILENE MESH LP 10X35 CM
1064895	OPTILENE MESH LP 20X20 CM
1064705UNI	OPTILENE MESH LP 15 X 15 CM
1064715UNI	OPTILENE MESH LP 7,5 X 15 CM
1064725UNI	OPTILENE MESH LP 10 X 15 CM
1064735UNI	OPTILENE MESH LP 5 X 10 CM
1064765UNI	OPTILENE MESH LP HOLE/TAILS 4,5 X 10 CM
1064855UNI	OPTILENE MESH LP 15 X 20 CM
1964705	OPTILENE MESH LP BLUE 15 X 15 CM
1964715	OPTILENE MESH LP BLUE 7,5 X 15 CM
1964725	OPTILENE MESH LP BLUE 10 X 15 CM
1964735	OPTILENE MESH LP BLUE 5 X 10 CM
1964755	OPTILENE MESH LP BLUE 7,5 X 7,5 CM
1964765	OPTILENE MESH LP BLUE HOLE/TAILS 4,5 X 10 CM
1964775	OPTILENE MESH LP BLUE HOLE/TAILS 6 X 14 CM
1964825	OPTILENE MESH LP BLUE PRESHAPE 4,5 X 10 CM
1964845	OPTILENE MESH LP BLUE PRESHAPE 6 X 14 CM
1964855	OPTILENE MESH LP BLUE 15 X 20 CM
1964865	OPTILENE MESH LP BLUE 6X35CM
1964875	OPTILENE MESH LP BLUE 8X35 CM
1964885	OPTILENE MESH LP BLUE 10X35 CM
1964895	OPTILENE MESH LP BLUE 20X20 CM
1964705UNI	OPTILENE MESH LP BLUE 15 X 15 CM

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Reference	Product Name / Description
1964715UNI	OPTILENE MESH LP BLUE 7,5 X 15 CM
1964725UNI	OPTILENE MESH LP BLUE 10 X 15 CM
1964735UNI	OPTILENE MESH LP BLUE 5 X 10 CM
1964755UNI	OPTILENE MESH LP BLUE 7,5 X 7,5 CM
1964765UNI	OPTILENE MESH LP BLUE HOLE/TAILS 4,5 X 10 CM
1964775UNI	OPTILENE MESH LP BLUE HOLE/TAILS 6 X 14 CM
1964825UNI	OPTILENE MESH LP BLUE PRESHAPE 4,5 X 10 cm
1964845UNI	OPTILENE MESH LP BLUE PRESHAPE 6 X 14 cm
1964855UNI	OPTILENE MESH LP BLUE 15 X 20 CM
1964865UNI	OPTILENE MESH LP BLUE 6X35CM
1964875UNI	OPTILENE MESH LP BLUE 8X35 CM
1964885UNI	OPTILENE MESH LP BLUE 10X35 CM
1964895UNI	OPTILENE MESH LP BLUE 20X20 CM

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

Title: DoC Optilene 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: Ibañez, Heliazar (ibanhees)  
Title: SU-RA-ES04 Regulatory Affairs Technician  
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UserName: Orús, Silvia Salut (orussies)  
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