

**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 (cm) 4.5x9.5; 4.5x10; 5x10; 5x30; 6x12.5; 6x14; 7.5x15; 7.5x7.5; 10x15; 15x15; 20x30; 26x36; 30x30
<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

**DECLARATION OF CONFORMITY****DECLARACION DE CONFORMIDAD / KONFORMITÄTSERKLÄRUNG****Reference                      Product Name / Description**

1065020	OPTILENE MESH 5 X 10 CM
1065030	OPTILENE MESH 7,5 X 15 CM
1065040	OPTILENE MESH 10 X 15 CM
1065050	OPTILENE MESH 5 X 30 CM
1065060	OPTILENE MESH 26 X 36 CM
1065070	OPTILENE MESH 7,5 X 7,5 CM
1065080	OPTILENE MESH 15 X 15 CM
1065090	OPTILENE MESH 30 X 30 CM
1065100	OPTILENE MESH KEYHOLE 4,5 X 9,5 CM
1065110	OPTILENE MESH KEYHOLE 6 X 12,5 CM
1065120	OPTILENE MESH PRESHAPE 4,5 X 10 CM
1065130	OPTILENE MESH PRESHAPE 6 X 14 CM
1065140	OPTILENE MESH HOLE/TAILS 4,5 X 10 CM
1065150	OPTILENE MESH HOLE/TAILS 6 X 14 CM
1065160	OPTILENE MESH 20X30 CM
1065020UNI	OPTILENE MESH 5 X 10 CM
1065030UNI	OPTILENE MESH 7,5 X 15 CM
1065040UNI	OPTILENE MESH 10 X 15 CM
1065050UNI	OPTILENE MESH 5 X 30 CM
1065060UNI	OPTILENE MESH 26 X 36 CM
1065070UNI	OPTILENE MESH 7,5 X 7,5 CM
1065080UNI	OPTILENE MESH 15 X 15 CM
1065090UNI	OPTILENE MESH 30 X 30 CM
1065100UNI	OPTILENE MESH KEYHOLE 4,5 X 9,5 CM
1065110UNI	OPTILENE MESH KEYHOLE 6 X 12,5 CM
1065120UNI	OPTILENE MESH PRESHAPE 4,5 X 10 CM
1065130UNI	OPTILENE MESH PRESHAPE 6 X 14 CM
1065140UNI	OPTILENE MESH HOLE/TAILS 4,5 X 10 CM
1065150UNI	OPTILENE MESH HOLE/TAILS 6 X 14 CM
1065160UNI	OPTILENE MESH 20X30 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).

Effective

Title: DoC Optilene Mesh 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

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UserName: Orús, Silvia Salut (orussies)  
Title: Global Regulatory Affairs Manager CoE CT  
Date: Wednesday, 06 April 2022, 15:51 W. Europe Daylight Time  
Meaning: Approve Document

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UserName: Turón, Pau (turopaes)  
Title: VP R&D B. Braun Group (Spain)  
Date: Thursday, 07 April 2022, 15:57 W. Europe Daylight Time  
Meaning: Approve Document

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