

**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	PREMILENE MESH (cm) 3x10;4.5x9.5;4.5x10;5x10;5x30;6x12.5;6x14; 7.5x7.5;7.5x15;8x12;10x15;15x15;26x36;30x30
<b>PRODUCT CODE /</b> Código de producto / Artikelnummer	Detailed information enclosed Información detallada adjunta Detaillierte Informationen beigelegt
<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
1064305	PREMILENE MESH 3 X 10 CM
1064315	PREMILENE MESH 5 X 10 CM
1064325	PREMILENE MESH KEYHOLE 4,5 X 9,5 CM
1064335	PREMILENE MESH KEYHOLE 6 X 12,5 CM
1064345	PREMILENE MESH PRESHAPE 4,5 X 10 CM
1064365	PREMILENE MESH PRESHAPE 6 X 14 CM
1064375	PREMILENE MESH HOLE/TAILS 6 X 14 CM
1064385	PREMILENE MESH HOLE/TAILS 4,5 X 10 CM
1064395	PREMILENE MESH 8X12CM PRECUT
1064415	PREMILENE MESH 7,5 X 7,5 CM
1064425	PREMILENE MESH 7,5 X 15 CM
1064435	PREMILENE MESH 15 X 15 CM
1064445	PREMILENE MESH 5 X 30 CM
1064455	PREMILENE MESH 30 X 30 CM
1064465	PREMILENE MESH 26 X 36 CM
1064495	PREMILENE MESH 10 X 15 CM
1064305UNI	PREMILENE MESH 3 X 10 CM
1064315UNI	PREMILENE MESH 5 X 10 CM
1064325UNI	PREMILENE MESH KEYHOLE 4,5 X 9,5 CM
1064335UNI	PREMILENE MESH KEYHOLE 6 X 12,5 CM
1064345UNI	PREMILENE MESH PRESHAPE 4,5 X 10 CM
1064365UNI	PREMILENE MESH PRESHAPE 6 X 14 CM
1064375UNI	PREMILENE MESH HOLE/TAILS 6 X 14 CM
1064385UNI	PREMILENE MESH HOLE/TAILS 4,5 X 10 CM
1064415UNI	PREMILENE MESH 7,5 X 7,5 CM
1064425UNI	PREMILENE MESH 7,5 X 15 CM
1064435UNI	PREMILENE MESH 15 X 15 CM
1064445UNI	PREMILENE MESH 5 X 30 CM
1064455UNI	PREMILENE MESH 30 X 30 CM

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Reference	Product Name / Description
1064465UNI	PREMILENE MESH 26 X 36 CM
1064495UNI	PREMILENE MESH 10 X 15 CM
1064535L	PREMILENE MESH 10X15CM SLIT COVER LEFT
1064545R	PREMILENE MESH 10X15CM SLIT COVER RIGHT

<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 Premilene 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)  
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