

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

PREMILENE MESH PLUG

small;medium;large;x-large

PRODUCT CODE /

Código de producto / Artikelnummer

Detailed information enclosed

Información detallada adjunta

Detaillierte Informationen beigelegt

CLASS, RULE /

Clase, regla / Risikoklasse, Regel (Annex IX MDD)

IIb, 8

CONFORMITY ASSESSMENT ROUTE /

Evaluación de la conformidad /

Konformitätsbewertungsverfahren nach

Annex II.3 of the COUNCIL DIRECTIVE 93/42/ECC 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

16-05-2011

CE Certificate/

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, 4th April 2022ⁱ

This document is signed electronically

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Reference	Product Name / Description
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1064603	PREMILENE MESH PLUG SMALL WITHOUT ONLAY
1064605	PREMILENE MESH PLUG SMALL WITH ONLAY
1064613	PREMILENE MESH PLUG MEDIUM WITHOUT ONLAY
1064615	PREMILENE MESH PLUG MEDIUM WITH ONLAY
1064623	PREMILENE MESH PLUG LARGE WITHOUT ONLAY
1064625	PREMILENE MESH PLUG LARGE WITH ONLAY
1064633	PREMILENE MESH PLUG XLARGE WITHOUT ONLAY
1064635	PREMILENE MESH PLUG X-LARGE WITH ONLAY
1064603UNI	PREMILENE MESH PLUG SMALL WITHOUT ONLAY
1064605UNI	PREMILENE MESH PLUG SMALL WITH ONLAY
1064613UNI	PREMILENE MESH PLUG MEDIUM WITHOUT ONLAY
1064615UNI	PREMILENE MESH PLUG MEDIUM WITH ONLAY
1064623UNI	PREMILENE MESH PLUG LARGE WITHOUT ONLAY
1064625UNI	PREMILENE MESH PLUG LARGE WITH ONLAY
1064633UNI	PREMILENE MESH PLUG XLARGE WITHOUT ONLAY
1064635UNI	PREMILENE MESH PLUG X-LARGE WITH ONLAY

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

Title: DoC Premilene Mesh Plug 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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Date: Thursday, 07 April 2022, 15:56 W. Europe Daylight Time
Meaning: Approve Document
