

**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

SAFIL MESH

(cm) 12x8; 15x15; 25x15; 28x18; 30x30

**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

**CONFORMITY ASSESSMENT ROUTE /**Evaluación de la conformidad /  
Konformitätsbewertungsverfahren nachAnnex II. 3 and Annex 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

30-03-2010

**CE Certificate/**

Certificado CE / EG Bescheinigung

G7 025701 0094 Rev. 00 // 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
1065500	SAFIL MESH 30 X 30 CM
1065501	SAFIL MESH 15 X 15 CM
1065503	SAFIL MESH 28 X 18 CM
1065504	SAFIL MESH 25 X 15 CM
1065508	SAFIL MESH 12X8 CM
1065508UNI	SAFIL MESH 12X8 CM

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

Title: DoC Safil 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, 10:52 W. Europe Daylight Time  
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UserName: Orús, Silvia Salut (orussies)  
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UserName: Turón, Pau (turopaes)  
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