

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

Eso-SPONGE

OV 13 & 15 mm

PRODUCT CODE /

Código de producto / Artikelnummer

Detailed information enclosed

Información detallada adjunta

Detaillierte Informationen beigelegt

CLASS, RULE /

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

IIa, 5

CONFORMITY ASSESSMENT ROUTE /

Evaluación de la conformidad /

Konformitätsbewertungsverfahren nach

Annex II.3 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

14-05-2014

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, 25.03.2022ⁱ

This document is signed electronically

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Reference	Product Name / Description
5526540	Eso-SPONGE, ov 15 mm
5526550	Eso-SPONGE, ov 13 mm

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

Title: DoC Eso-SPONGE 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: Pinto, Constanza Maria (pintcoes)
Title: SU-RA-ES04 Regulatory Affairs Technician
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Meaning: Document signed as Author

UserName: Turón, Pau (turopaes)
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Date: Tuesday, 29 March 2022, 11:29 W. Europe Daylight Time
Meaning: Approve Document

UserName: Orús, Silvia Salut (orussies)
Title: Global Regulatory Affairs Manager CoE CT
Date: Wednesday, 30 March 2022, 23:31 W. Europe Daylight Time
Meaning: Approve Document
