

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

PREMIPATCH PTFE PLEDGETS

(mm) 3x3; 6x3; 6x5; 9x5; 16x7

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 nach

Annex II.3 and II.4 of the COUNCIL DIRECTIVE

93/42/ECC of 14 June 1993 concerning medical

devices

NOTIFIED BODY /

Organismo Notificado / Benannte Stelle

TÜV Süd Product Service

Ridlerstrasse, 65, 80339 München, Germany

NB No. 0123

START OF CE MARKING /

Inicio marca CE / Beginn der CE-Kennzeichnung

20-07-2010

CE Certificate/

Certificado CE / EG Bescheinigung

G7 025701 0063 Rev. 01 // 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
C0027983	PREMIPATCH 6PTFE SOFT PLEDGETS 6X5MMPEEL
C0027990	PREMIPATCH 6PTFE SOFT PLEDGETS 3X3MMPEEL
C0027991	PREMIPATCH 6PTFE SOFT PLEDGETS 6X3MMPEEL
C0027992	PREMIPATCH 6PTFE SOFT PLEDGETS 9X5MMPEEL
C0027993	PREMIPATCH 2PTFE SOFT PLEDGET 16X7MMPEEL
C0027994	PREMIPATCH 6PTFE FIRM PLEDGETS 9X5MMPEEL
C0027995	PREMIPATCH 6PTFE FIRM PLEDGETS 6X3MMPEEL
C0027996	PREMIPATCH 6PTFE FIRM PLEDGETS 3X3MMPEEL
G0027995	PREMIPATCH 6PTFE FIRM PLEDGETS 6X3MMPEEL

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

Title: DoC Premipatch PTFE Pledgets 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
Date: Tuesday, 05 April 2022, 08:40 W. Europe Daylight Time
Meaning: Document signed as Author

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Date: Wednesday, 06 April 2022, 15:47 W. Europe Daylight Time
Meaning: Approve Document

UserName: Turón, Pau (turopaes)
Title: VP R&D B. Braun Group (Spain)
Date: Thursday, 07 April 2022, 12:28 W. Europe Daylight Time
Meaning: Approve Document
