

**DECLARATION OF CONFORMITY**  
**DECLARACION DE CONFORMIDAD / KONFORMITÄTSEKLRUNG**

<b>MANUFACTURER /</b> Fabricante / Hersteller	B. Braun Surgical, S.A. Ctra. de Terrassa, 121 08191 Rubí (Barcelona), Spain
<b>PRODUCT /</b> Producto / Produkte	Gelita Tampon (cm) 1x1x1;1,5x1,5x1;8x2x1;8x5x1
<b>PRODUCT CODE /</b> Código de producto / Artikelnummer	Detailed information enclosed Información detallada adjunta Detaillierte Informationen beigefügt
<b>CLASS, RULE /</b> Clase, regla / Risikoklasse, Regel (Annex IX MDD)	III, 8 and 17
<b>CONFORMITY ASSESSMENT ROUTE /</b> 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
<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	19-12-2011
<b>CE Certificate/</b> Certificado CE / EG Bescheinigung	G7 16 10 25701 067

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, 8<sup>th</sup> February 2021**

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Reference	Product Name / Description
2070014	GELITA – TAMPON 1x1x1 CM
2070103	GELITA – TAMPON 1x1x1 CM
2070154	GELITA – TAMPON 1,5x1,5x1 CM
2070600	GELITA – TAMPON 8x5x1 CM
2070707	GELITA – TAMPON 8x2x1 CM

Title: DoC Gelita Initiator: Maria ? Gutierrez

This document is signed electronically in compliance with the B. Braun electronic signature policies and procedures by following persons:

UserName: Pinto, Constanza (pintcoes)  
Title: SU-RA-ES04 Regulatory Affairs Technician  
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