

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

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|--|---|
| <b>MANUFACTURER /</b><br>Fabricante / Hersteller   | B. Braun Surgical, S.A.<br>Ctra. de Terrassa, 121<br>08191 Rubí (Barcelona), Spain                      |
| <b>PRODUCT /</b><br>Producto / Produkte  | LYOSTYPT, SANGUSTOP<br>(cm) 3x5;5x3;5x8;5x30;10x12  |
| <b>PRODUCT CODE /</b><br>Código de producto / Artikelnummer  | Detailed information enclosed<br>Información detallada adjunta<br>Detaillierte Informationen beigelegt  |
| <b>CLASS, RULE /</b><br>Clase, regla / Risikoklasse, Regel (Annex IX MDD)                                      | III, 8  |
| <b>CONFORMITY ASSESSMENT ROUTE /</b><br>Evaluación de la conformidad /<br>Konformitätsbewertungsverfahren nach | Annex II.3 and II.4 of the COUNCIL DIRECTIVE<br>93/42/ECC of 14 June 1993 concerning medical<br>devices |
| <b>NOTIFIED BODY /</b><br>Organismo Notificado / Benannte Stelle   | TÜV Sud Product Service<br>Ridlerstrasse, 65, 80339 München, Germany<br>NB No 0123                      |
| <b>START OF CE MARKING /</b><br>Inicio marca CE / Beginn der CE-Kennzeichnung                                  | 19-12-2011  |
| <b>CE Certificate/</b><br>Certificado CE / EG Bescheinigung  | G7A0 025701 0092 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, 25.03.2022<sup>i</sup>**

This document is signed electronically

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| Reference | Product Name / Description |
|-----------|----------------------------|
|-----------|----------------------------|

|         |                       |
|---------|-----------------------|
| 1069020 | LYOSTYPT 5 X 8 CM     |
| 1069039 | LYOSTYPT 10 X 12 CM   |
| 1069128 | LYOSTYPT 3 X 5 CM     |
| 1069152 | LYOSTYPT 5 X 8 CM     |
| 1069209 | LYOSTYPT 10 X 12 CM   |
| 1069306 | LYOSTYPT 5 X 30 CM    |
| 1069400 | SANGUSTOP 5 CM X 8 CM |
| 1069500 | SANGUSTOP 5 CM X 8 CM |
| 1069550 | SANGUSTOP 5 CM X 8 CM |
| 1069600 | SANGUSTOP 5 CM X 3 CM |

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

Title: DoC Lyosypt Sangustop Initiator: Maria del Carmen ? Gutierrez

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

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