

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	HISTOACRYL (mL) 0,5
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 Sud Product Service Ridlerstrasse, 65, 80339 München, Germany NB No 0123
START OF CE MARKING / Inicio marca CE / Beginn der CE-Kennzeichnung	19-12-2011
CE Certificate/ Certificado CE / EG Bescheinigung	G7 18 02 25701 080 // 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
1050044	HISTOACRYL BLUE 0,5 ML
1050052	HISTOACRYL BLUE 0,5 ML
1050060	HISTOACRYL TRANSLUCENT 0,5 ML
1050071	HISTOACRYL TRANSLUCENT 0,5 ML
9381104	HISTOACRYL BLUE 0,5 ML

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

Title: DoC Histoacryl 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)
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