

**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 nachAnnex 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

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**

[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

Title: DoC Histoacryl 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  
Date: Tuesday, 09 February 2021, 09:43 W. Europe Daylight Time  
Meaning: Document signed as Author

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UserName: Turón, Pau (turopaes)  
Title: VP R&D B. Braun Group (Spain)  
Date: Wednesday, 10 February 2021, 22:53 W. Europe Daylight Time  
Meaning: Approve Document

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UserName: Orus, Silvia Salud (orussies)  
Title: Global Regulatory Affairs Manager CoE CT  
Date: Thursday, 11 February 2021, 20:30 W. Europe Daylight Time  
Meaning: Approve Document

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