

**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 FLEXIBLE

(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)

IIa, 4

**CONFORMITY ASSESSMENT ROUTE /**Evaluación de la conformidad /  
Konformitätsbewertungsverfahren nachAnnex II.3 of the Council Directive 93/42/EEC 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

27-11-2012

**CE Certificate/**

Certificado CE / EG Bescheinigung

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
1051250	Histoacryl Flexible blue 0,5 ml 5 ampoules
1051260	Histoacryl Flexible blue 0,5 ml 10 ampoules

<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 Histoacryl Flexible 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, 29 March 2022, 11:28 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: Tuesday, 29 March 2022, 11:35 W. Europe Daylight Time  
Meaning: Approve Document

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UserName: Orús, Silvia Salut (orussies)  
Title: Global Regulatory Affairs Manager CoE CT  
Date: Wednesday, 30 March 2022, 23:32 W. Europe Daylight Time  
Meaning: Approve Document

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