

**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

SURGICAL LOOP

(mm) 1.2; 1.5; 2.5; 4; 8

**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, 6

**CONFORMITY ASSESSMENT ROUTE /**

Evaluación de la conformidad /

Konformitätsbewertungsverfahren nach

Annex II.3 of the COUNCIL DIRECTIVE 93/42/ECC of

14 June 1993 concerning medical devices

**NOTIFIED BODY /**

Organismo Notificado / Benannte Stelle

TÜV Süd Product Service

Ridlerstrasse, 65, 80339 München, Germany

NB No. 0123

**START OF CE MARKING /**

Inicio marca CE / Beginn der CE-Kennzeichnung

16-05-2011

**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, 07.01.2022<sup>i</sup>**

This document is signed electronically

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Reference	Product Name / Description
B1094920	SURG LOOP COTON WHITE 4MM 2X38CM ADCE
B1095013	SURG LOOP SILIC ROJO 1.5MM 2X45CM ADCE
B1095021	SURG LOOP SILIC BLUE 1.5MM 2X45CM ADCE
B1095030	SURG LOOP SILIC YELLOW 1.5MM 2X45CM ADCE
B1095048	SURG LOOP SILIC WHITE 1.5MM 2X45CM ADCE
B1095110	SURG LOOP SILIC ROJO 2.5MM 2X45CM ADCE
B1095129	SURG LOOP SILIC BLUE 2.5MM 2X45CM ADCE
B1095137	SURG LOOP SILIC YELLOW 2.5MM 2X45CM ADCE
B1095145	SURG LOOP SILIC WHITE 2.5MM 2X45CM ADCE
B1095218	SURG LOOP SILIC ROJO 1.5MM 75CM ADCE
B1095226	SURG LOOP SILIC BLUE 1.5MM 75CM ADCE
B1095234	SURG LOOP SILIC YELLOW 1.5MM 75CM ADCE
B1095242	SURG LOOP SILIC WHITE 1.5MM 75CM ADCE
B1095510	SURG LOOP SILIC ROJO 2.5MM 75CM ADCE
B1095528	SURG LOOP SILIC AZUL 2.5MM 75CM ADCE
B1095536	SURG LOOP SILIC YELLOW 2.5MM 75CM ADCE
B1095544	SURG LOOP SILIC WHITE 2.5MM 75CM ADCE
B1095625	SURG LOOP COTON WHITE 4MM 75CM ADCE
B1095633	SURG LOOP COTON BLUE 4MM 75CM ADCE
B1095641	SURG LOOP COTON VIOLETA 4MM 75CM ADCE
B1095650	SURG LOOP COTON GREEN 4MM 75CM ADCE
B1095668	SURG LOOP COTON WHITE 8MM 75CM ADCE
B1095676	SURG LOOP COTON BLUE 8MM 75CM ADCE

<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.9).

Title: DoC Surgical Loop 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: Cot, Agustin (cotagues)  
Title: SU-QM-ES04 Senior Regulatory Affairs  
Date: Monday, 10 January 2022, 11:10 W. Europe Daylight Time  
Meaning: Document signed as Author

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UserName: Turón, Pau (turopaes)  
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