

**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

STEELEX ELECTRODE SET

USP 3/0 – USP 0

**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, 7

**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 Süd Product Service

Ridlerstrasse, 65, 80339 München, Germany

NB No. 0123

**START OF CE MARKING /**

Inicio marca CE / Beginn der CE-Kennzeichnung

24-04-2019

**CE Certificate/**

Certificado CE / EG Bescheinigung

G7 025701 0087 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
C0990008	STEE ELE SETW/B3/0 2X60CM HR13MGS51VBKSG
C0992026	STEE EL BLU 3/0 60CM HRC17/GS65V BK SGCE
C0992038	STEE EL BLU 3/0 60CM HR17/GS65V BRK SGCE
C0992041	STEE EL BLU 3/0 60CM HRC26/GS65V BK SGCE
C0992045	STEE EL BLU 2/0 2X60 HR26/GS65V BRK SGCE
C0992046	STEE EL BLU 3/0 60CM HR26/GS65V BRK SGCE
C0992054	STEE EL BLU 3/0 60CM HR17/GS51V BRK SGCE
C0992062	STEE EL BLU 3/0 60CM HRT17/GS65V BK SGCE
C0992070	STEE EL BLU 3/0 60CM HRT26/GS65V BK SGCE
C0992097	STEE EL BLU 2/0 60CM HR26/GS65V BRK SGCE
C0992100	STEE EL BLU 0 60CM HR26/GS65V BRK SGCE
C0992131	STEE EL BLU 2/0(3)60CM HR26/GS90V BRK SG
C0992702	STEE EL W/B 3/0 2X60 HR17/GS51V BRK SGCE
C0992703	STEE EL W/B 3/0 2X60 HR17/GS65V BRK SGCE
C0992704	STEE EL W/B 3/0 2X60 HR26/GS65V BRK SGCE
C0992720	STEE EL W/B 3/0(2)2X60CM HR26/GS90VBRKSG
C0992721	STEE EL W/B 2/0(3)2X60CM HR26/GS90VBRKSG
G0992097	STEE EL BLU 2/0 60CM HR26/GS65V BRK SGCE
X0992046	STEE EL BLU 3/0 60CM HR26/GS65V BRK SGCE

<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 Steelex Electrode Set 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, 05 April 2022, 08:42 W. Europe Daylight Time  
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UserName: Orús, Silvia Salut (orussies)  
Title: Global Regulatory Affairs Manager CoE CT  
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UserName: Turón, Pau (turopaes)  
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Meaning: Approve Document

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