

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

USP 5/0 – USP 7

PRODUCT CODE /

Código de producto / Artikelnummer

Detailed information enclosed

Información detallada adjunta

Detaillierte Informationen beigelegt

CLASS, RULE /

Clase, regla / Risikoklasse, Regel (Annex IX MDD)

IIb, 8

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, 12.05.2022ⁱ

This document is signed electronically

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Reference	Product Name / Description
G0092061	STEELEX MONOFILAR 2/0 (3) 150CM ARO DDP
G0092070	STEELEX MONOFILAR 0 (3,5) 150CM ARO DDP
G0092096	STEELEX MONOFILAR 1 (4) 150CM ARO DDP
G0092100	STEELEX MONOFILAR 2 (5) 150CM ARO DDP
G0094153	STEELEX MONOFILAR 1 (4) 250CM ARO DDP
G0094269	STEELEX MONOFILAR 2/0 (3) 3X60CM LPCE
G0094277	STEELEX MONOFILAR 0 (3,5) 3X60CM LPCE
G0094285	STEELEX MONOFILAR 1 (4) 3X60CM LPCE
G0098442	STEELEX MONOFILAR 3/0 (2) 6X45CM LPCE
G0098469	STEELEX MONOFILAR 2/0 (3) 6X45CM LPCE
G0098477	STEELEX MONOFILAR 0 (3,5) 6X45CM LPCE
G0098485	STEELEX MONOFILAR 1 (4) 6X45CM LPCE
G0098493	STEELEX MONOFILAR 2 (5) 6X45CM LPCE
G0098507	STEELEX MONOFILAR 3 (6) 6X45CM LPCE
G0098515	STEELEX MONOFILAR 5 (7) 6X45CM LPCE
G0098523	STEELEX MONOFILAR 6 (8) 6X45CM LPCE
G0098531	STEELEX MONOFILAR 7 (9) 6X45CM LPCE
G0112046	STEELEX POLIFILAR 4/0 (1,5)150CM ARO DDP
G0112054	STEELEX POLIFILAR 3/0 (2) 150CM ARO DDP
G0592471	STEELEX MONOFILAR 2/0 (3) 75CM DS30 DDP
G0592793	STEELEX MONOFILAR 2/0 (3) 45CM DS39 DDP
G0592960	STEELEX MONOFILAR 0 (3,5) 75CM HS37S SOW
G0593019	STEELEX MONOFILAR 0(3,5)4X45CM HR26 LPCE
G0593020	STEELEX MONOFILAR 1(4) 4X45CM HR26 LPCE
G0593052	STEELEX MONOFILAR 1(4)4X45CM HR37SS LPCE
G0593508	STEELEX MONOFILAR 1 (4) 45CM HS26S SOW
G0594350	STEELEX MONOFILAR 3/0 (2) 75CM DS24 DDP
G0595209	STEELEX MONOFILAR 4/0 (1,5)75CM DS19 DDP
G0595217	STEELEX MONOFILAR 3/0 (2) 75CM DS19 DDP
G0595230	STEELEX MONOFILAR 2 (5) 60CM DS45 DDP
G0595950	STEELEX MONOFILAR 2/0 (3) 60CM HS37S SOW
G0599409	STEELEX MONOFILAR 2 (5) 75CM 2XDS60 SOW
G0599417	STEELEX MONOFILAR 3 (6) 75CM 2XDS60 SOW
G0610283	STEELEX POLIFILAR 5/0 (1) 75CM HR22 DDP
G0610461	STEELEX POLIFILAR 3/0 (2) 75CM HR30 DDP
G0612197	STEELEX POLIFILAR 5/0 (1) 45CM DS19 DDP
G0612340	STEELEX POLIFILA 4/0 (1,5) 45CM DS24 DDP

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Reference	Product Name / Description
G0612359	STEELEX POLIFILAR 3/0 (2) 45CM DS24 DDP
G0612413	STEELEX POLIFILAR 3/0 (2) 45CM HS26 DDP
G0613410	STEELEX POLIFILAR 1 (4) 45CM HRT40 DDP
B0112046	STEELEX POLIFILAR 4/0 (1.5)150CM ARO DDP
B0612340	STEELEX POLIFILAR 4/0 (1,5)45CM DS24 DDP
B0612413	STEELEX POLIFILAR 3/0 (2) 45CM HS26 DDP
G0094137	STEELEX MONOFILAR 2/0 (3) 250CM ARO DDP
G0612472	STEELEX POLIFILAR 2/0 (3) 45CM DS30 DDP

ⁱ DoC has been signed after 26th of May 2021, due to clause 6.6 of SOP/31/OP/005 (v.9).

Title: DoC Steelex 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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