

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 STERNUM SET

USP 1 to 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, 15.03.2022ⁱ

This document is signed electronically

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Reference	Product Name / Description
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G0617144	STEELEX STE SET 1(4)4X45CM HRC37SS(M) LP
G0617835	STEELEX STE SET 1 (4) 4X45CM HRS40 LPCE
G0617851	STEELEX STE SET 1(4)4X45CM HRS40AXIALPCE
G0617142	STEELEX STE SET 2(5)4X45CM HRC37SS(M) LP
G0617143	STEELEX STE SET 2(5)2X45CM HRC37SS(M) LP
G0617780	STEELEX STE SET 2 (5) 4X45CM HRS48 LPCE
G0617838	STEELEX STE SET 2 (5) 4X45CM HRS40 LPCE
G0617839	STEELEX STE SET 2 (5) 5X45CM HRS40 LPCE
G0617848	STEELEX STE SET 2(5)4X45 HRS40 AXIA LPCE
G0617681	STEELEX STE SET 4 (6) 4X45CM HS48 LPCE
G0617784	STEELEX STE SET 4 (6) 4X45CM HRS48 LPCE
G0617792	STEELEX STE SET 4(6)4X45 HRS48 AXIA LPCE
G0617854	STEELEX STE SET 4 (6) 4X45CM HRS40 LPCE
G0610008	STEELEX STE SET 5 (7) 75CM HRS60 SOW
G0617006	STEELEX STE SET 5(7) 75CM HS55 AXIAL SOW
G0617040	STEELEX STE SET 5(7)75CM HRS60AXIAL SOW
G0617545	STEELEX STE SET 5 (7)45CM HRS48 AXIA SOW
G0617555	STEELEX STE SET 5 (7) 45CM HRS48 SOW
G0617563	STEELEX STE SET 5 (7)75CM HRS48 AXIA SOW
G0617579	STEELEX STE SET 5 (7) 75CM HRS48 SOW
G0617864	STEELEX STE SET 5 (7) 45CM HRS60 SOW
G0617865	STEELEX STE SET 5 (7)45CM HRS60 AXIA SOW
G0610017	STEELEX STE SET 5 (7) 6X45CM HRC48 (M)LP
G0617020	STEELEX STE SET 5 (7) 75CM HRS55 LPCE
G0617130	STEELEX STE SET 5 (7)2X45CM HRC48(M)LPCE
G0617134	STEELEX STE SET 5(7)4X75CM HRC48 (M) LP
G0617135	STEELEX STE SET 5(7)4X45CM HRC48 (M) LP
G0617559	STEELEX STE SET 5 (7) 8X45CM HRS48 LPCE
G0617682	STEELEX STE SET 5(7)2X75 HS55 AXIA LPCE
G0617717	STEELEX STE SET 5 (7) 4X45CM HRS48 LPCE
G0617718	STEELEX STE SET 5 (7) 5X45CM HRS48 LPCE
G0617733	STEELEX STE SET 5(7)4X45 HRS48 AXIA LPCE
G0617741	STEELEX STE SET 5(7)4X45 HRS60 AXIA LPCE
G0617742	STEELEX STE SET 5(7)4X45CM HRS60 LPCE

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Reference	Product Name / Description
G0617743	STEELEX STE SET 5 (7) 5X45CM HRS60 LPCE
G0617749	STEELEX STE SET 5 (7) 4X45CM HRN48 LPCE
G0617750	STEELEX STE SET 5(7)2X75 HRS60 AXIA LPCE
G0617776	STEELEX STE SET 5 (7) 2X75CM HRS60 LPCE
G0617880	STEEL STE SET5(7)2X45HRN48+2X45HRS48CBLP
G0617995	STEEL STE SET5(7)1X45HRS48+3X45HRN48CBLP
G0617546	STEELEX STE SET 6 (8)45CM HRS48 AXIA SOW
G0617556	STEELEX STE SET 6 (8) 45CM HRS48 SOW
G0610018	STEELEX STE SET 6 (8) 6X45CM HRC48 (M)LP
G0610167	STEELEX STE SET 6 (8) 4X45CM HRC48 (M)LP
G0617703	STEELEX STE SET 6 (8) 2X45CM HRN48 LPCE
G0617706	STEELEX STE SET 6 (8) 2X45CM HRS48 LPCE
G0617737	STEELEX STE SET 6 (8) 6X45CM HRS60 LPCE
G0617806	STEELEX STE SET 6(8)4X45 HRS48 AXIA LPCE
G0617813	STEELEX STE SET 6 (8) 4X45CM HRN48 LPCE
G0617814	STEELEX STE SET 6 (8) 4X45CM HRS48 LPCE
G0617815	STEELEX STE SET 6 (8) 5X45CM HRS48 LPCE
G0617881	STEEL STE SET6(8)2X45HRN48+2X45HRS48CBLP
G0617901	STEEL STE SET6(8)4X45HRN48+2X45HRS48CBLP
G0617996	STEEL STE SET6(8)1X45HRS48+3X45HRN48CBLP
G0617550	STEELEX STE SET 7 (9) 4X45CM HRN48 LPCE
G0617736	STEELEX STE SET 7 (9) 6X45CM HRS60 LPCE
G0617795	STEELEX STE SET 7 (9) 4X45CM HRS48 LPCE
G0617796	STEELEX STE SET 7(9)4X45 HRS48 AXIA LPCE
G0617798	STEELEX STE SET 7 (9) 5X45CM HRS48 LPCE
G0617802	STEELEX STE SET 7 (9) 4X75CM HRN48 LPCE
G0617804	STEELEX STE SET 7 (9) 5X45CM HRN48 LPCE
G0617882	STEEL STE SET7(9)2X45HRN48+2X45HRS48CBLP
G0617966	STEELEX STE SET 7 (9) 4X45CM HRC48 LPCE
G0617580	STEELEX STE SET 6 (8) 75CM HRS48 SOW

ⁱ DoC has been signed after 26th of May 2021, due to clause 6.6 of SOP/31/OP/005 (v.10).

Effective

Title: DoC Steelex Sternum 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: Wednesday, 16 March 2022, 10:34 W. Europe Daylight Time
Meaning: Document signed as Author

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Date: Wednesday, 16 March 2022, 11:15 W. Europe Daylight Time
Meaning: Approve Document

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Date: Wednesday, 16 March 2022, 18:29 W. Europe Daylight Time
Meaning: Approve Document
