

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	MONOMAX USP 3/0 – USP 1
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,8
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 Sud Product Service Ridlerstrasse, 65, 80339 München, Germany NB No 0123
START OF CE MARKING / Inicio marca CE / Beginn der CE-Kennzeichnung	30-03-2010
CE Certificate/ Certificado CE / EG Bescheinigung	G7 025701 0083 Rev.01 // 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, 25.03.2022ⁱ

This document is signed electronically

DECLARATION OF CONFORMITY**DECLARACION DE CONFORMIDAD / KONFORMITÄTSEKLRÄRUNG**

Reference	Product Name / Description
G0041006	MONOMAX VIOLET 1(4)150CM FRT65 LOOP(MDDP
G0041249	MONOMAX VIOLET 2/0 (3) 70CM HR26 (M)
X0041118	MONOMAX VIOLET 0(3,5)150CM HR48LOOP MDDP
X0041185	MONOMAX VIOLET 1(4)150CM HRT40S LOOPMDDP
X0041203	MONOMAX VIOLET 1(4)150CM HRT43S LOOPMDDP
X0041231	MONOMAX VIOLET 1(4)200CM HRT48 LOOP(MDDP
B0041119	MONOMAX VIOLET 1(4)150CM HR48 LOOP(M)DDP
B0041222	MONOMAX VIOLET 1(4)150CM HRT48 LOOP(MDDP
B0041077	MONOMAX VIOLET 1(4)150CM HR40S LOOP(MDDP
B0041560	MONOMAX VIOLET 1 (4) 70CM JRC30S (M) DDP
B0041444	MONOMAX VIOLET 2/0 (3) 150CM HR26 (M)DDP
B0041249	MONOMAX VIOLET 2/0 (3) 70CM HR26 (M)
B0041076	MONOMAX VIOLET 0(3,5)150CM HR40SLOOPMDDP
B0041024	MONOMAX VIOLET 0 (3,5) 90CM HR37 (M)DDP
B0041046	MONOMAX VIOLET 0 (3,5) 90CM HR37S (M)DDP
B0041442	MONOMAX VIOLET 0 (3,5) 150CM HR26S(M)DDP
B0041887	MONOMAX VIOLET 2/0 (3) 70CM FR26 (M) DDP
B0041441	MONOMAX VIOLET 0 (3,5) 150CM HR26 (M)DDP
B0041098	MONOMAX VIOLET 1 (4) 90CM HR40S (M)DDP
B0041185	MONOMAX VIOLET 1(4)150CM HRT40S LOOPMDDP
B0041138	MONOMAX VIOLET 1 (4) 90CM HR48 (M)DDP
B0041203	MONOMAX VIOLET 1(4)150CM HRT43S LOOPMDDP
B0041118	MONOMAX VIOLET 0(3,5)150CM HR48LOOP MDDP
B0041097	MONOMAX VIOLET 0 (3,5) 90CM HR40S (M)DDP
B0041047	MONOMAX VIOLET 1 (4) 90CM HR37S (M)DDP
B0041455	MONOMAX VIOLET 0 (3,5) 150CM HR30 (M)DDP
B0041038	MONOMAX VIOLET 0(3,5)150CM HR37 LOOPMDDP
B0041453	MONOMAX VIOLET 2/0 (3) 150CM HR30 (M)DDP
B0041043	MONOMAX VIOLET 0 (3,5) 150CM HR37S(M)DDP
B0041258	MONOMAX VIOLET 2/0 (3) 90CM HR26 (M)
B0041415	MONOMAX VIOLET 2/0 (3) 70CM HR22 (M) DDP
B0041184	MONOMAX VIOLET0(3,5)150CM HRT40SLOOPMDDP
G0041119	MONOMAX VIOLET 1(4)150CM HR48 LOOP(M)DDP
B0041148	MONOMAX VIOLET 1(4)150CM HR65 LOOP(M)DDP
B0041166	MONOMAX VIOLET 1(4)150CM HRN50 LOOP(MDDP
B0041005	MONOMAX VIOLET 0(3,5)150CM FRT65LOOPMDDP
B0041889	MONOMAX VIOLET 1 (4) 70CM FR26 (M) DDP
B0041888	MONOMAX VIOLET 0 (3,5) 70CM FR26 (M) DDP

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Reference	Product Name / Description
B0041035	MONOMAX VIOLET 0 (3,5) 70CM HR37S (M)DDP
B0041221	MONOMAX VIOLET 0(3,5)150CM HRT48LOOPMDDP
B0041117	MONOMAX VIOLET 2/0(3)150 HR48 LOOP(M)DDP
B0041175	MONOMAX VIOLET 2/0 (3) 70CM HRT26 (M)DDP
B0041025	MONOMAX VIOLET 1 (4) 90CM HR37 (M)DDP
B0041034	MONOMAX VIOLET 2/0 (3) 70CM HR37S (M)DDP
B0041241	MONOMAX VIOLET 1 (4) 90CM HRT48 (M)DDP
B0041067	MONOMAX VIOLET 1 (4) 90CM HR40 (M)DDP
B0041066	MONOMAX VIOLET 0 (3,5) 90CM HR40 (M)DDP
B0041033	MONOMAX VIOLET 0 (3,5) 70CM HR22S (M)DDP
B0041194	MONOMAX VIOLET 1 (4) 90CM HRT40S (M)DDP
B0041472	MONOMAX VIOLET 2/0 (3) 150CM HRT30(M)DDP
B0041280	MONOMAX VIOLET 1 (4) 90CM HR30 (M)
B0041147	MONOMAX VIOLET 0(3,5)150CM HR65LOOP MDDP
B0041015	MONOMAX VIOLET 2/0 (3) 70CM HR37 (M)DDP
B0041278	MONOMAX VIOLET 2/0 (3) 90CM HR30 (M)
B0041250	MONOMAX VIOLET 0 (3,5) 70CM HR26 (M) DDP
B0041036	MONOMAX VIOLET 1 (4) 70CM HR37S (M)DDP
G0041148	MONOMAX VIOLET 1(4)150CM HR65 LOOP(M)DDP
B0041157	MONOMAX VIOLET 1(4)150CM HR76 LOOP(M)DDP
B0041212	MONOMAX VIOLET 1 (4) 90CM HRT43S (M)DDP
B0041307	MONOMAX VIOLET 1(4)150CM HR43 LOOP(M)DDP
B0041137	MONOMAX VIOLET 0 (3,5) 90CM HR48 (M)DDP
B0041240	MONOMAX VIOLET 0 (3,5) 90CM HRT48 (M)DDP
B0041006	MONOMAX VIOLET 1(4)150CM FRT65 LOOP(MDDP
B0041176	MONOMAX VIOLET 0 (3,5) 70CM HRT26 (M)DDP
B0041057	MONOMAX VIOLET 2/0 (3) 70CM HR40 (M)DDP
B0041002	MONOMAX VIOLET 0 (3,5) 70CM HR26S (M)DDP
G0041077	MONOMAX VIOLET 1(4)150CM HR40S LOOP(MDDP
B0041269	MONOMAX VIOLET 1 (4) 70CM HR30 (M)
G0041076	MONOMAX VIOLET 0(3,5)150CM HR40SLOOPMDDP
B0041087	MONOMAX VIOLET 0 (3,5) 70CM HR40S (M)DDP
B0041042	MONOMAX VIOLET 2/0 (3) 150CM HR37S(M)DDP
B0041108	MONOMAX VIOLET 1 (4) 90CM HR43S (M)DDP
B0041352	MONOMAX VIOLET 0 (3,5) 90CM HRT40 (M)DDP
B0041088	MONOMAX VIOLET 1 (4) 70CM HR40S (M)DDP
B0041325	MONOMAX VIOLET 1(4)200CM HR48 LOOP(M)
G0041138	MONOMAX VIOLET 1 (4) 90CM HR48 (M)DDP
B0041434	MONOMAX VIOLET 1(4)180CM HRT48 LOOP(MDDP

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Reference	Product Name / Description
B0041001	MONOMAX VIOLET 1(4)150CM FR65 LOOP(M)DDP
B0041571	MONOMAX VIOLET 1 (4)70CM FR40 LOOP(M)DDP
B0041463	MONOMAX VIOLET 2/0 (3) 150CM HRT26(M)DDP
G0041203	MONOMAX VIOLET 1(4)150CM HRT43S LOOPMDDP
B0041231	MONOMAX VIOLET 1(4)200CM HRT48 LOOP(MDDP
B0041267	MONOMAX VIOLET 2/0 (3) 70CM HR30 (M)
G0041118	MONOMAX VIOLET 0(3,5)150CM HR48LOOP MDDP
G0041035	MONOMAX VIOLET 0 (3,5) 70CM HR37S (M)DDP
B0041107	MONOMAX VIOLET 0 (3,5) 90CM HR43S (M)DDP
B0041086	MONOMAX VIOLET 2/0 (3) 70CM HR40S (M)DDP
X0041024	MONOMAX VIOLET 0 (3,5) 90CM HR37 (M)DDP
G0041015	MONOMAX VIOLET 2/0 (3) 70CM HR37 (M)DDP
X0041025	MONOMAX VIOLET 1 (4) 90CM HR37 (M)DDP
X0041046	MONOMAX VIOLET 0 (3,5) 90CM HR37S (M)DDP
X0041067	MONOMAX VIOLET 1 (4) 90CM HR40 (M)DDP
X0041076	MONOMAX VIOLET 0(3,5)150CM HR40SLOOPMDDP
X0041077	MONOMAX VIOLET 1(4)150CM HR40S LOOP(MDDP
X0041119	MONOMAX VIOLET 1(4)150CM HR48 LOOP(M)DDP
X0041138	MONOMAX VIOLET 1 (4) 90CM HR48 (M)DDP
X0041148	MONOMAX VIOLET 1(4)150CM HR65 LOOP(M)DDP
X0041222	MONOMAX VIOLET 1(4)150CM HRT48 LOOP(MDDP
X0041249	MONOMAX VIOLET 2/0 (3) 70CM HR26 (M) DDP
X0041442	MONOMAX VIOLET 0 (3,5) 150CM HR26S(M)DDP
X0041444	MONOMAX VIOLET 2/0 (3) 150CM HR26 (M)DDP
X0041455	MONOMAX VIOLET 0 (3,5) 150CM HR30 (M)DDP
B0041003	MONOMAX VIOLET 1 (4) 90CM HR65 (M) DDP
B0041004	MONOMAX VIOLET 1(4)70CM SKR48 LOOP(M)DDP
B0041037	MONOMAX VIOLET 2/0 (3) 90CM HR20 (M)DDP
B0041044	MONOMAX VIOLET 2/0 (3) 150CM HR37 (M)DDP
B0041128	MONOMAX VIOLET 2/0 (3) 70CM HR48 (M) DDP
B0041298	MONOMAX VIOLET 0 (3,5) 70CM HR43 (M)
B0041310	MONOMAX VIOLET 1(4)120CM HRT48 LOP(M)DDP
B0041344	MONOMAX VIOLET 1 (4) 70CM HRT40 (M)
B0041416	MONOMAX VIOLET 0 (3,5) 70CM HR22 (M) DDP
B0041573	MONOMAX VIOLET 1 (4)90CM FR40 LOOP(M)DDP
B0041053	MONOMAX VIOLET 3/0 (2) 70CM HR22 (M)DDP
B0041092	MONOMAX VIOLET 3/0 (2) 70CM HR26 (M)DDP
B0041112	MONOMAX VIOLET 3/0 (2) 70CM HR26S(M)DDP
B0041124	MONOMAX VIOLET 3/0 (2) 70CM HR30 (M)DDP

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Reference	Product Name / Description
B0041153	MONOMAX VIOLET 3/0 (2) 70CM HR37S(M)DDP
B0041982	MONOMAX VIOLET 3/0 (2) 70CM HR17 (M)DDP

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

Title: DoC Monomax 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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