

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

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, 17th February 2021

[This document is signed electronically](#)

DECLARATION OF CONFORMITY
DECLARACION DE CONFORMIDAD / KONFORMITÄTSERKLÄRUNG

Reference	Product Name / Description
B0041001	MONOMAX VIOLET 1(4)150CM FR65 LOOP(M)DDP
B0041002	MONOMAX VIOLET 0 (3,5) 70CM HR26S (M)DDP
B0041003	MONOMAX VIOLET 1 (4) 90CM HR65 (M) DDP
B0041004	MONOMAX VIOLET 1(4)70CM SKR48 LOOP(M)DDP
B0041005	MONOMAX VIOLET 0(3,5)150CM FRT65LOOPMDDP
B0041006	MONOMAX VIOLET 1(4)150CM FRT65 LOOP(MDDP
B0041015	MONOMAX VIOLET 2/0 (3) 70CM HR37 (M)DDP
B0041024	MONOMAX VIOLET 0 (3,5) 90CM HR37 (M)DDP
B0041025	MONOMAX VIOLET 1 (4) 90CM HR37 (M)DDP
B0041033	MONOMAX VIOLET 0 (3,5) 70CM HR22S (M)DDP
B0041034	MONOMAX VIOLET 2/0 (3) 70CM HR37S (M)DDP
B0041035	MONOMAX VIOLET 0 (3,5) 70CM HR37S (M)DDP
B0041036	MONOMAX VIOLET 1 (4) 70CM HR37S (M)DDP
B0041037	MONOMAX VIOLET 2/0 (3) 90CM HR20 (M)DDP
B0041038	MONOMAX VIOLET 0(3,5)150CM HR37 LOOPMDDP
B0041042	MONOMAX VIOLET 2/0 (3) 150CM HR37S(M)DDP
B0041043	MONOMAX VIOLET 0 (3,5) 150CM HR37S(M)DDP
B0041044	MONOMAX VIOLET 2/0 (3) 150CM HR37 (M)DDP
B0041046	MONOMAX VIOLET 0 (3,5) 90CM HR37S (M)DDP
B0041047	MONOMAX VIOLET 1 (4) 90CM HR37S (M)DDP
B0041053	MONOMAX VIOLET 3/0 (2) 70CM HR22 (M)DDP
B0041057	MONOMAX VIOLET 2/0 (3) 70CM HR40 (M)DDP
B0041066	MONOMAX VIOLET 0 (3,5) 90CM HR40 (M)DDP
B0041067	MONOMAX VIOLET 1 (4) 90CM HR40 (M)DDP
B0041076	MONOMAX VIOLET 0(3,5)150CM HR40SLOOPMDDP
B0041077	MONOMAX VIOLET 1(4)150CM HR40S LOOP(MDDP
B0041086	MONOMAX VIOLET 2/0 (3) 70CM HR40S (M)DDP
B0041087	MONOMAX VIOLET 0 (3,5) 70CM HR40S (M)DDP
B0041088	MONOMAX VIOLET 1 (4) 70CM HR40S (M)DDP
B0041092	MONOMAX VIOLET 3/0 (2) 70CM HR26 (M)DDP
B0041097	MONOMAX VIOLET 0 (3,5) 90CM HR40S (M)DDP
B0041098	MONOMAX VIOLET 1 (4) 90CM HR40S (M)DDP
B0041107	MONOMAX VIOLET 0 (3,5) 90CM HR43S (M)DDP
B0041108	MONOMAX VIOLET 1 (4) 90CM HR43S (M)DDP
B0041112	MONOMAX VIOLET 3/0 (2) 70CM HR26S(M)DDP
B0041117	MONOMAX VIOLET 2/0(3)150 HR48 LOOP(M)DDP
B0041118	MONOMAX VIOLET 0(3,5)150CM HR48LOOP MDDP
B0041119	MONOMAX VIOLET 1(4)150CM HR48 LOOP(M)DDP
B0041124	MONOMAX VIOLET 3/0 (2) 70CM HR30 (M)DDP

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

Reference	Product Name / Description
B0041128	MONOMAX VIOLET 2/0 (3) 70CM HR48 (M) DDP
B0041137	MONOMAX VIOLET 0 (3,5) 90CM HR48 (M)DDP
B0041138	MONOMAX VIOLET 1 (4) 90CM HR48 (M)DDP
B0041147	MONOMAX VIOLET 0(3,5)150CM HR65LOOP MDDP
B0041148	MONOMAX VIOLET 1(4)150CM HR65 LOOP(M)DDP
B0041153	MONOMAX VIOLET 3/0 (2) 70CM HR37S(M)DDP
B0041157	MONOMAX VIOLET 1(4)150CM HR76 LOOP(M)DDP
B0041166	MONOMAX VIOLET 1(4)150CM HRN50 LOOP(MDDP
B0041175	MONOMAX VIOLET 2/0 (3) 70CM HRT26 (M)DDP
B0041176	MONOMAX VIOLET 0 (3,5) 70CM HRT26 (M)DDP
B0041184	MONOMAX VIOLETO(3,5)150CM HRT40SLOOPMDDP
B0041185	MONOMAX VIOLET 1(4)150CM HRT40S LOOPMDDP
B0041194	MONOMAX VIOLET 1 (4) 90CM HRT40S (M)DDP
B0041203	MONOMAX VIOLET 1(4)150CM HRT43S LOOPMDDP
B0041212	MONOMAX VIOLET 1 (4) 90CM HRT43S (M)DDP
B0041221	MONOMAX VIOLET 0(3,5)150CM HRT48LOOPMDDP
B0041222	MONOMAX VIOLET 1(4)150CM HRT48 LOOP(MDDP
B0041231	MONOMAX VIOLET 1(4)200CM HRT48 LOOP(MDDP
B0041240	MONOMAX VIOLET 0 (3,5) 90CM HRT48 (M)DDP
B0041241	MONOMAX VIOLET 1 (4) 90CM HRT48 (M)DDP
B0041249	MONOMAX VIOLET 2/0 (3) 70CM HR26 (M)
B0041250	MONOMAX VIOLET 0 (3,5) 70CM HR26 (M) DDP
B0041258	MONOMAX VIOLET 2/0 (3) 90CM HR26 (M)
B0041267	MONOMAX VIOLET 2/0 (3) 70CM HR30 (M)
B0041269	MONOMAX VIOLET 1 (4) 70CM HR30 (M)
B0041278	MONOMAX VIOLET 2/0 (3) 90CM HR30 (M)
B0041280	MONOMAX VIOLET 1 (4) 90CM HR30 (M)
B0041298	MONOMAX VIOLET 0 (3,5) 70CM HR43 (M)
B0041307	MONOMAX VIOLET 1(4)150CM HR43 LOOP(M)DDP
B0041310	MONOMAX VIOLET 1(4)120CM HRT48 LOP(M)DDP
B0041325	MONOMAX VIOLET 1(4)200CM HR48 LOOP(M)DDP
B0041344	MONOMAX VIOLET 1 (4) 70CM HRT40 (M)
B0041348	MONOMAX VIOLET 3/0 (2) 70CM HS26S(M)DDP
B0041352	MONOMAX VIOLET 0 (3,5) 90CM HRT40 (M)DDP
B0041415	MONOMAX VIOLET 2/0 (3) 70CM HR22 (M) DDP
B0041416	MONOMAX VIOLET 0 (3,5) 70CM HR22 (M) DDP
B0041434	MONOMAX VIOLET 1(4)180CM HRT48 LOOP(MDDP
B0041441	MONOMAX VIOLET 0 (3,5) 150CM HR26 (M)DDP
B0041442	MONOMAX VIOLET 0 (3,5) 150CM HR26S(M)DDP

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

Reference	Product Name / Description
B0041444	MONOMAX VIOLET 2/0 (3) 150CM HR26 (M)DDP
B0041453	MONOMAX VIOLET 2/0 (3) 150CM HR30 (M)DDP
B0041455	MONOMAX VIOLET 0 (3,5) 150CM HR30 (M)DDP
B0041463	MONOMAX VIOLET 2/0 (3) 150CM HRT26(M)DDP
B0041472	MONOMAX VIOLET 2/0 (3) 150CM HRT30(M)DDP
B0041560	MONOMAX VIOLET 1 (4) 70CM JRC30S (M) DDP
B0041571	MONOMAX VIOLET 1 (4)70CM FR40 LOOP(M)DDP
B0041573	MONOMAX VIOLET 1 (4)90CM FR40 LOOP(M)DDP
B0041845	MONOMAX VIOLET 3/0 (2) 45CM DS19 (M)DDP
B0041855	MONOMAX VIOLET 3/0 (2) 45CM DS24 (M)DDP
B0041863	MONOMAX VIOLET 3/0 (2)45CM DSMP19(M)DDP
B0041879	MONOMAX VIOLET 3/0 (2)45CM DSMP24(M)DDP
B0041887	MONOMAX VIOLET 2/0 (3) 70CM FR26 (M) DDP
B0041888	MONOMAX VIOLET 0 (3,5) 70CM FR26 (M) DDP
B0041889	MONOMAX VIOLET 1 (4) 70CM FR26 (M) DDP
B0041982	MONOMAX VIOLET 3/0 (2) 70CM HR17 (M)DDP
G0041006	MONOMAX VIOLET 1(4)150CM FRT65 LOOP(MDDP
G0041015	MONOMAX VIOLET 2/0 (3) 70CM HR37 (M)DDP
G0041035	MONOMAX VIOLET 0 (3,5) 70CM HR37S (M)DDP
G0041076	MONOMAX VIOLET 0(3,5)150CM HR40SLOOPMDDP
G0041077	MONOMAX VIOLET 1(4)150CM HR40S LOOP(MDDP
G0041118	MONOMAX VIOLET 0(3,5)150CM HR48LOOP MDDP
G0041119	MONOMAX VIOLET 1(4)150CM HR48 LOOP(M)DDP
G0041138	MONOMAX VIOLET 1 (4) 90CM HR48 (M)DDP
G0041148	MONOMAX VIOLET 1(4)150CM HR65 LOOP(M)DDP
G0041203	MONOMAX VIOLET 1(4)150CM HRT43S LOOPMDDP
G0041249	MONOMAX VIOLET 2/0 (3) 70CM HR26 (M)
X0041006	MONOMAX VIOLET 1(4)150CM FRT65 LOOP(MDDP
X0041024	MONOMAX VIOLET 0 (3,5) 90CM HR37 (M)DDP
X0041025	MONOMAX VIOLET 1 (4) 90CM HR37 (M)DDP
X0041035	MONOMAX VIOLET 0 (3,5) 70CM HR37S (M)DDP
X0041046	MONOMAX VIOLET 0 (3,5) 90CM HR37S (M)DDP
X0041047	MONOMAX VIOLET 1 (4) 90CM HR37S (M)DDP
X0041057	MONOMAX VIOLET 2/0 (3) 70CM HR40 (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
X0041087	MONOMAX VIOLET 0 (3,5) 70CM HR40S (M)DDP
X0041097	MONOMAX VIOLET 0 (3,5) 90CM HR40S (M)DDP

DECLARATION OF CONFORMITY
DECLARACION DE CONFORMIDAD / KONFORMITÄTSEKLRÄRUNG

Reference	Product Name / Description
X0041098	MONOMAX VIOLET 1 (4) 90CM HR40S (M)DDP
X0041117	MONOMAX VIOLET 2/0(3)150 HR48 LOOP(M)DDP
X0041118	MONOMAX VIOLET 0(3,5)150CM HR48LOOP MDDP
X0041119	MONOMAX VIOLET 1(4)150CM HR48 LOOP(M)DDP
X0041128	MONOMAX VIOLET 2/0 (3) 70CM HR48 (M) DDP
X0041137	MONOMAX VIOLET 0 (3,5) 90CM HR48 (M)DDP
X0041138	MONOMAX VIOLET 1 (4) 90CM HR48 (M)DDP
X0041147	MONOMAX VIOLET 0(3,5)150CM HR65LOOP MDDP
X0041148	MONOMAX VIOLET 1(4)150CM HR65 LOOP(M)DDP
X0041157	MONOMAX VIOLET 1(4)150CM HR76 LOOP(M)DDP
X0041166	MONOMAX VIOLET 1(4)150CM HRN50 LOOP(MDDP
X0041175	MONOMAX VIOLET 2/0 (3) 70CM HRT26 (M)DDP
X0041184	MONOMAX VIOLET 0(3,5)150CM HRT40SLOOPMDDP
X0041185	MONOMAX VIOLET 1(4)150CM HRT40S LOOPMDDP
X0041194	MONOMAX VIOLET 1 (4) 90CM HRT40S (M)DDP
X0041203	MONOMAX VIOLET 1(4)150CM HRT43S LOOPMDDP
X0041221	MONOMAX VIOLET 0(3,5)150CM HRT48LOOPMDDP
X0041222	MONOMAX VIOLET 1(4)150CM HRT48 LOOP(MDDP
X0041231	MONOMAX VIOLET 1(4)200CM HRT48 LOOP(MDDP
X0041241	MONOMAX VIOLET 1 (4) 90CM HRT48 (M)DDP
X0041249	MONOMAX VIOLET 2/0 (3) 70CM HR26 (M) DDP
X0041258	MONOMAX VIOLET 2/0 (3) 90CM HR26 (M) DDP
X0041280	MONOMAX VIOLET 1 (4) 90CM HR30 (M) DDP
X0041343	MONOMAX VIOLET 0 (3,5) 70CM HRT40 (M)DDP
X0041352	MONOMAX VIOLET 0 (3,5) 90CM HRT40 (M)DDP
X0041369	MONOMAX VIOLET 0 (3,5) 70CM HRT43 (M)DDP
X0041378	MONOMAX VIOLET 0 (3,5) 90CM HRT43 (M)DDP
X0041396	MONOMAX VIOLET 1 (4) 70CM HRT48 (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

Title: DoC Monomax Initiator: Maria ? Gutierrez

This document is signed electronically in compliance with the B. Braun electronic signature policies and procedures by following persons:

UserName: Pinto, Constanza (pintcoes)
Title: SU-RA-ES04 Regulatory Affairs Technician
Date: Thursday, 18 February 2021, 11:51 W. Europe Daylight Time
Meaning: Document signed as Author

UserName: Orus, Silvia Salud (orussies)
Title: Global Regulatory Affairs Manager CoE CT
Date: Friday, 19 February 2021, 11:17 W. Europe Daylight Time
Meaning: Approve Document

UserName: Turón, Pau (turopaes)
Title: VP R&D B. Braun Group (Spain)
Date: Friday, 19 February 2021, 12:54 W. Europe Daylight Time
Meaning: Approve Document
