

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	DAGROFIL USP 6/0 - USP 5
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 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	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, 13.01.2022ⁱ

This document is signed electronically.

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Reference	Product Name / Description
B0342114	DAGROFIL GREEN 3 (6) 150CM
B0342122	DAGROFIL GREEN 4 (6) 150CM
B0342130	DAGROFIL GREEN 5 (7) 150CM DDP
B0344117	DAGROFIL GREEN 3 (6) 2X75CM DDP
B0344494	DAGROFIL GREEN 1 (4) 5X75CM DDP
B0346497	DAGROFIL GREEN 1 (4) 5X45CM DDP
B0346500	DAGROFIL GREEN 2 (5) 5X45CM DDP
B0346675	DAGROFIL GREEN 0 (3,5) 10X45CM DDP
B0346691	DAGROFIL GREEN 1 (4) 10X45CM DDP
B0842648	DAGROFIL GREEN 3 (6) 75CM HS40 DDP
C0342050	DAGROFIL GREEN 3/0 (2) 150CM DDP
C0342068	DAGROFIL GREEN 2/0 (3) 150CM DDP
C0342076	DAGROFIL GREEN 0 (3,5) 150CM DDP
C0342092	DAGROFIL GREEN 1 (4) 150CM DDP
C0342106	DAGROFIL GREEN 2 (5) 150CM DDP
C0342114	DAGROFIL GREEN 3 (6) 150CM DDP
C0342122	DAGROFIL GREEN 4 (6) 150CM DDP
C0344052	DAGROFIL GREEN 3/0 (2) 2X75CM DDP
C0344060	DAGROFIL GREEN 2/0 (3) 2X75CM DDP
C0344079	DAGROFIL GREEN 0 (3,5) 2X75CM DDP
C0344095	DAGROFIL GREEN 1 (4) 2X75CM DDP
C0344109	DAGROFIL GREEN 2 (5) 2X75CM DDP
C0344117	DAGROFIL GREEN 3 (6) 2X75CM DDP
C0346241	DAGROFIL GREEN 4/0 (1,5) 3X45CM DDP
C0346250	DAGROFIL GREEN 3/0 (2) 3X45CM DDP
C0346268	DAGROFIL GREEN 2/0 (3) 3X45CM DDP
C0346276	DAGROFIL GREEN 0 (3,5) 3X45CM DDP
C0346292	DAGROFIL GREEN 1 (4) 3X45CM DDP
C0346306	DAGROFIL GREEN 2 (5) 3X45CM DDP
C0346454	DAGROFIL GREEN 3/0 (2) 5X45CM DDP
C0346462	DAGROFIL GREEN 2/0 (3) 5X45CM DDP

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Reference	Product Name / Description
C0346470	DAGROFIL GREEN 0 (3,5) 5X45CM DDP
C0346640	DAGROFIL GREEN 4/0 (1,5) 10X45CM DDP
C0346659	DAGROFIL GREEN 3/0 (2) 10X45CM DDP
C0346667	DAGROFIL GREEN 2/0 (3) 10X45CM DDP
C0346675	DAGROFIL GREEN 0 (3,5) 10X45CM DDP
C0346861	DAGROFIL GREEN 2/0 (3) 17X45CM DDP
C0371248	DAGROFIL WHITE 5/0 (1) 100CM DDP
C0372102	DAGROFIL WHITE 2 (5) 150CM DDP
C0840130	DAGROFIL GREEN 4/0 (1,5) 75CM HR17 DDP
C0840149	DAGROFIL GREEN 3/0 (2) 75CM HR17 DDP
C0840157	DAGROFIL GREEN 2/0 (3) 75CM HR17 DDP
C0840297	DAGROFIL GREEN 4/0 (1,5) 75CM HR22 DDP
C0840300	DAGROFIL GREEN 3/0 (2) 75CM HR22 DDP
C0840319	DAGROFIL GREEN 2/0 (3) 75CM HR22 DDP
C0840416	DAGROFIL GREEN 3/0 (2) 75CM HR26 DDP
C0840424	DAGROFIL GREEN 2/0 (3) 75CM HR26 DDP
C0840432	DAGROFIL GREEN 0 (3,5) 75CM HR26 DDP
C0840440	DAGROFIL GREEN 2 (5) 75CM HR30 DDP
C0840459	DAGROFIL GREEN (2,5) 75CM HR30 DDP
C0840467	DAGROFIL GREEN 3/0 (2) 75CM HR30 DDP
C0840475	DAGROFIL GREEN 2/0 (3) 75CM HR30 DDP
C0840483	DAGROFIL GREEN 0 (3,5) 75CM HR30 DDP
C0840491	DAGROFIL GREEN 1 (4) 75CM HR26 DDP
C0840521	DAGROFIL GREEN 0 (3,5) 75CM HR37 DDP
C0840522	DAGROFIL GREEN 0 (3,5) 75CM HR37S DDP
C0840530	DAGROFIL GREEN 1 (4) 75CM HR37 DDP
C0840556	DAGROFIL GREEN 1 (4) 75CM HR30 DDP
C0841366	DAGROFIL GREEN 1 (4) 75CM DR22 DDP
C0841528	DAGROFIL GREEN 4/0 (1,5) 45CM GR19 DDP
C0841587	DAGROFIL GREEN 2/0 (3) 75CM DR32 DDP
C0841595	DAGROFIL GREEN 0 (3,5) 75CM DR32 DDP

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Reference	Product Name / Description
C0841609	DAGROFIL GREEN 1 (4) 75CM DR32 DDP
C0842125	DAGROFIL GREEN 5/0 (1) 45CM DS16 DDP
C0842192	DAGROFIL GREEN 5/0 (1) 45CM DS19 DDP
C0842206	DAGROFIL GREEN 4/0 (1,5) 45CM DS19 DDP
C0842214	DAGROFIL GREEN 3/0 (2) 45CM DS19 DDP
C0842222	DAGROFIL GREEN 2/0 (3) 45CM DS19 DDP
C0842249	DAGROFIL GREEN 0 (3,5) 75CM HS30 DDP
C0842257	DAGROFIL GREEN 1 (4) 75CM HS30 DDP
C0842265	DAGROFIL GREEN 2 (5) 75CM HS30 DDP
C0842273	DAGROFIL GREEN 1 (4) 75CM HS37S DDP
C0842281	DAGROFIL GREEN 1 (4) 75CM HS37 DDP
C0842303	DAGROFIL GREEN 3/0 (2) 45CM HS23 DDP
C0842354	DAGROFIL GREEN 3/0 (2) 75CM DS24 DDP
C0842362	DAGROFIL GREEN 2/0 (3) 75CM DS24 DDP
C0842427	DAGROFIL GREEN 2/0 (3) 75CM HS26 DDP
C0842478	DAGROFIL GREEN 2/0 (3) 75CM DS30 DDP
C0842486	DAGROFIL GREEN 0 (3,5) 75CM DS30 DDP
C0842494	DAGROFIL GREEN 1 (4) 75CM DS30 DDP
C0842583	DAGROFIL GREEN 0 (3,5) 75CM DS39 DDP
C0842591	DAGROFIL GREEN 1 (4) 75CM DS39 DDP
C0842664	DAGROFIL GREEN 2/0 (3) 75CM GS60 DDP
C0844140	DAGROFIL GREEN 4/0 (1,5) 45CM HRC17 DDP
C0844144	DAGROFIL GREEN 3/0 (2) 45CM HRT17 DDP
C0844149	DAGROFIL GREEN 3/0 (2) 45CM HRC17 DDP
C0844350	DAGROFIL GREEN 3/0 (2) 45CM HS18 DDP
C0844357	DAGROFIL GREEN 3/0 (2) 45CM DS24 DDP
C0844365	DAGROFIL GREEN 2/0 (3) 45CM DS24 DDP
C0844535	DAGROFIL GREEN 3/0 (2) 75CM HS21 DDP
C0845198	DAGROFIL GREEN 4/0 (1,5) 75CM DS16 DDP
C0846100	DAGROFIL GREEN 6/0(0,7)45CM DSMP11(M)DDP
C0846198	DAGROFIL GREEN 5/0 (1) 45CM DSMP13(M)DDP

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Reference	Product Name / Description
C0848060	DAGROFIL GREEN 6/0(0,7)45 2XDSMP11(M)DDP
C0849350	DAGROFIL GREEN 2/0 (3) 90CM 2XHRC26 DDP
C0849383	DAGROFIL GREEN 2/0 (3) 90CM 2XHRT26 DDP
C0850136	DAGROFIL WHITE 4/0 (1,5) 75CM HR17 DDP
C0850144	DAGROFIL WHITE 3/0 (2) 75CM HR17 DDP
C0850400	DAGROFIL WHITE 2/0 (3) 45CM DS24 DDP
C0850420	DAGROFIL WHITE 2/0 (3) 75CM HR26 DDP
C0852139	DAGROFIL WHITE 4/0 (1,5) 45CM DS16 DDP
C0852201	DAGROFIL WHITE 4/0 (1,5) 45CM DS19 DDP
C0852210	DAGROFIL WHITE 3/0 (2) 45CM DS19 DDP
C0854336	DAGROFIL WHITE 4/0(1,5)45CM DSMP13(M)DDP
C0854352	DAGROFIL WHITE 3/0 (2) 45CM DS24 DDP
C0858056	DAGROFIL WHITE 4/0 (1,5) 45CM 2XDS12 DDP
C0858188	DAGROFIL WHITE 4/0 (1,5) 45CM 2XDR12 DDP
G0341070	DAGROFIL GREEN 0 (3,5) 200CM DDP
G0341193	DAGROFIL GREEN (2,5) 250CM ARO DDP
G0341215	DAGROFIL GREEN 4/0 (1,5) 250CM ARO DDP
G0341223	DAGROFIL GREEN 3/0 (2) 250CM ARO DDP
G0341231	DAGROFIL GREEN 2/0 (3) 250CM ARO DDP
G0341240	DAGROFIL GREEN 0 (3,5) 250CM ARO DDP
G0341258	DAGROFIL GREEN 1 (4) 250CM ARO DDP
G0341266	DAGROFIL GREEN 2 (5) 250CM ARO DDP
G0341274	DAGROFIL GREEN 3 (6) 250CM ARO DDP
G0341282	DAGROFIL GREEN 4 (6) 250CM ARO DDP
G0371243	DAGROFIL WHITE 3/0 (2) 250CM ARO DDP
G0371244	DAGROFIL WHITE 2/0 (3) 250CM ARO DDP
G0371245	DAGROFIL WHITE 0 (3,5) 250CM ARO DDP
G0371246	DAGROFIL WHITE 1 (4) 250CM ARO DDP
G0371247	DAGROFIL WHITE 2 (5) 250CM ARO DDP
G0841528	DAGROFIL GREEN 4/0 (1,5) 45CM GR19 DDP
G0842214	DAGROFIL GREEN 3/0 (2) 45CM DS19 DDP

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Reference	Product Name / Description
G0844136	DAGROFIL GREEN 4/0 (1,5) 45CM HRT17 DDP
G0844144	DAGROFIL GREEN 3/0 (2) 45CM HRT17 DDP
G0848425	DAGROFIL GREEN 5/0 (1) 45CM 2XVLM8(M)DDP
G0848430	DAGROFIL GREEN 6/0(0,7)45CM 2XVLM8(M)DDP
G0848630	DAGROFIL GREEN 4/0(1,5)45CM 2XHLM8(M)DDP
G0858420	DAGROFIL WHITE 5/0 (1) 45CM 2XVLM8(M)DDP
G0858630	DAGROFIL WHITE 4/0(1,5)45CM 2XVLM8(M)DDP
X0341274	DAGROFIL GREEN 3 (6) 250CM ARO DDP
X0342068	DAGROFIL GREEN 2/0 (3) 150CM DDP
X0342114	DAGROFIL GREEN 3 (6) 150CM DDP
X0344095	DAGROFIL GREEN 1 (4) 2X75CM DDP
X0344109	DAGROFIL GREEN 2 (5) 2X75CM DDP
X0346241	DAGROFIL GREEN 4/0 (1,5) 3X45CM DDP
X0346250	DAGROFIL GREEN 3/0 (2) 3X45CM DDP
X0346268	DAGROFIL GREEN 2/0 (3) 3X45CM DDP
X0346292	DAGROFIL GREEN 1 (4) 3X45CM DDP
X0346306	DAGROFIL GREEN 2 (5) 3X45CM DDP
X0346462	DAGROFIL GREEN 2/0 (3) 5X45CM DDP
X0346470	DAGROFIL GREEN 0 (3,5) 5X45CM DDP
X0840130	DAGROFIL GREEN 4/0 (1,5) 75CM HR17 DDP
X0840300	DAGROFIL GREEN 3/0 (2) 75CM HR22 DDP
X0840319	DAGROFIL GREEN 2/0 (3) 75CM HR22 DDP
X0840424	DAGROFIL GREEN 2/0 (3) 75CM HR26 DDP
X0840432	DAGROFIL GREEN 0 (3,5) 75CM HR26 DDP
X0840483	DAGROFIL GREEN 0 (3,5) 75CM HR30 DDP
X0840521	DAGROFIL GREEN 0 (3,5) 75CM HR37 DDP
X0840556	DAGROFIL GREEN 1 (4) 75CM HR30 DDP
X0841528	DAGROFIL GREEN 4/0 (1,5) 45CM GR19 DDP
X0842192	DAGROFIL GREEN 5/0 (1) 45CM DS19 DDP
X0842206	DAGROFIL GREEN 4/0 (1,5) 45CM DS19 DDP
X0842214	DAGROFIL GREEN 3/0 (2) 45CM DS19 DDP

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Reference	Product Name / Description
X0842257	DAGROFIL GREEN 1 (4) 75CM HS30 DDP
X0842265	DAGROFIL GREEN 2 (5) 75CM HS30 DDP
X0842303	DAGROFIL GREEN 3/0 (2) 45CM HS23 DDP
X0842354	DAGROFIL GREEN 3/0 (2) 75CM DS24 DDP
X0842362	DAGROFIL GREEN 2/0 (3) 75CM DS24 DDP
X0842478	DAGROFIL GREEN 2/0 (3) 75CM DS30 DDP
X0842486	DAGROFIL GREEN 0 (3,5) 75CM DS30 DDP
X0842494	DAGROFIL GREEN 1 (4) 75CM DS30 DDP
X0844136	DAGROFIL GREEN 4/0 (1,5) 45CM HRT17 DDP
X0844144	DAGROFIL GREEN 3/0 (2) 45CM HRT17 DDP
X0844365	DAGROFIL GREEN 2/0 (3) 45CM DS24 DDP
X0845198	DAGROFIL GREEN 4/0 (1,5) 75CM DS16 DDP
X0849383	DAGROFIL GREEN 2/0 (3) 90CM 2XHRT26 DDP
X0850144	DAGROFIL WHITE 3/0 (2) 75CM HR17 DDP
X0852139	DAGROFIL WHITE 4/0 (1,5) 45CM DS16 DDP
X0852210	DAGROFIL WHITE 3/0 (2) 45CM DS19 DDP

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

Title: DoC Dagrofil 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: Calderone, Vittorio (caldvaes)
Title: SU-DM-ES04 Regulatory Affairs Technician
Date: Friday, 14 January 2022, 13:14 W. Europe Daylight Time
Meaning: Document signed as Author

UserName: Turón, Pau (turopaes)
Title: VP R&D B. Braun Group (Spain)
Date: Monday, 17 January 2022, 08:09 W. Europe Daylight Time
Meaning: Approve Document

UserName: Orús, Silvia Salut (orussies)
Title: Global Regulatory Affairs Manager CoE CT
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Meaning: Approve Document
