

**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

DAFILON

USP 8/0 to 11/0

**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

20-07-2010

**CE Certificate/**

Certificado CE / EG Bescheinigung

G7 025701 0059 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, 26.05.2022<sup>i</sup>**

This document is signed electronically

## DECLARATION OF CONFORMITY

### DECLARACION DE CONFORMIDAD / KONFORMITÄTSERKLÄRUNG

Reference	Product Name / Description
G1110012	DAFILON BK 11/0(0,1)15CM DLM4 125MIC BLT
C0977225	DAFILON BLACK 7/0 (0,5) 45CM DSMP7(M)DDP
G1110225	DAFILON BLK 10/0(0,2)30CM DLM6S 200M BLT
G1110250	DAFILON BK 8/0(0,4)30CM DLM6S 200MIC BLT
G1110326	DAFILON BK 10/0(0,2)30CM 2XPLM5 150M BLT
G1110740	DAFILON BLACK 8/0 (0,4) 15CM DR6 (M)BLT
G1110802	DAFILON BK 10/0(0,2)12CM PLM5 150MIC BLT
G1111140	DAFILON BK 9/0(0,3)15CM DRCM5 100MIC BLT
G1111213	DAFILON BK 11/0(0,1)30CM 2XDLM6 150M BLT
G1111248	DAFILON BK 8/0(0,4)45CM 2XDLM6S 200M BLT
G1111272	DAFILON BK 10/0(0,2)15CM 2XDLM6 150M BLT
G1111337	DAFILON BK 8/0(0,4)30CM 2XVLM6S 200M BLT
G1111434	DAFILON BLK 9/0(0,3)15CM DRM5 100MIC BLT
G1111693	DAFILON BLACK 8/0(0,4)15CM DLM5 150MIBLT
G1111922	DAFILON BK 10/0(0,2)20CM 2XPLM5 150M BLT
G1117041	DAFILON BLK 10/0(0,2)15CM DRM3 50MIC BLT
G1118013	DAFILON BK 10/0(0,2)15CM DRM6 140MIC BLT
G1118025	DAFILON BK 9/0(0,3)15CM 2XDRM6 140MI BLT
G1118030	DAFILON BLK 8/0(0,4)15CM HRM8 140MIC BLT
G1118032	DAFILON BK 9/0(0,3)30CM 2XDLM5 150MI BLT
G1118048	DAFILON BLK 10/0(0,2)15CM DRCM3 100M BLT
G1118064	DAFILON BK 11/0 (0,1) 5CM DRM3 50MIC BLT
G1118072	DAFILON BLK 10/0(0,2) 5CM DRM3 50MIC BLT
G1118080	DAFILON BLK 11/0(0,1)10CM DRM4 70MIC BLT
G1118099	DAFILON BLK 10/0(0,2)10CM DRM4 70MIC BLT
G1118110	DAFILON BK 10/0(0,2)15CM DRM5 100MI BLT
G1118129	DAFILON BLK 10/0(0,2)10CM DRM4S 140M BLT
G1118137	DAFILON BK 9/0 (0,3) 10CM DRM4S 140M BLT
G1118138	DAFILON BLK 8/0(0,4)10CM DRM4S 140M BLT
G1118161	DAFILON BLK 9/0(0,3)15CM DRM6 140MIC BLT
G1118170	DAFILON BLK 8/0(0,4)15CM DRM6 140MIC BLT
G1118250	DAFILON BK 10/0(0,2)15CM 2XDRM5 100M BLT
G1118331	DAFILON BLK 10/0(0,2)7CM DLM6 150MIC BLT
G1118366	DAFILON BLK 11/0(0,1)10CM DRM3 50MIC BLT

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

Reference	Product Name / Description
G1118374	DAFILON BK 11/0 (0,1) 8CM HRM4 70MIC BLT
G1118390	DAFILON BK 8/0(0,4) 15CM PRM6 140MIC BLT
G1118404	DAFILON BK 10/0(0,2)15CM 2XDRCM4 140 BLT
G1118412	DAFILON BK 10/0(0,2)8CM PRCM5 100MIC BLT
G1118420	DAFILON BK 9/0(0,3)13CM PRCM5 100MIC BLT
G1118439	DAFILON BK 8/0(0,4)15CM PRCM6 140MIC BLT
G1118447	DAFILON BK 10/0(0,2)3CM 2XPRCM5 100M BLT
G1118455	DAFILON BK 8/0(0,4)15CM 2XDRCM6 140M BLT
G1118463	DAFILON BK 10/0 (0,2)8CM PRM4 70MIC BLT
G1118471	DAFILON BK 9/0 (0,3) 13CM PRM5 100MI BLT
G1118528	DAFILON BK 10/0(0,2)45CM 2XDLM6 150M BLT
G1118530	DAFILON BK 8/0(0,4)30CM 2XHLM8 200MI BLT
G1118535	DAFILON BK 9/0(0,3)30CM 2XDRM6 140MI BLT
G1118560	DAFILON BK 8/0 (0,4) 15CM HLM8 200MI BLT
G1118579	DAFILON BK 8/0(0,4)15CM DLM6S 200MIC BLT
G1118609	DAFILON BK 10/0(0,2)30CM 2XHLM6 150M BLT
G1118617	DAFILON BK 9/0(0,3)30CM 2XHLM6 150MI BLT
G1118625	DAFILON BK 10/0(0,2)15CM HLM6 150MIC BLT
G1118633	DAFILON BK 9/0(0,3) 15CM HLM6 150MIC BLT
G1118641	DAFILON BK 10/0(0,2)30CM HLM6 150MIC BLT
G1118650	DAFILON BLK 9/0(0,3)30CM HLM6 150MIC BLT
G1118668	DAFILON BK 8/0(0,4) 5CM 2XDLM6 150MI BLT
G1118684	DAFILON BK 10/0(0,2)15CM DLM5 150MIC BLT
G1118706	DAFILON BK 10/0(0,2)30CM 2XDLM6 150M BLT
G1118714	DAFILON BK 9/0(0,3)30CM 2XDLM6 150MI BLT
G1118722	DAFILON BK 10/0(0,2)15CM DLM6 150MIC BLT
G1118730	DAFILON BLK 9/0(0,3)15CM DLM6 150MIC BLT
G1118737	DAFILON BLK 10/0(0,2)30CM 2XHLM8 200MBLT
G1118738	DAFILON BLK 9/0(0,3)30CM 2XHLM8 200MIBLT
G1118749	DAFILON BK 10/0(0,2)30CM DLM6 150MIC BLT
G1118757	DAFILON BK 9/0(0,3) 30CM DLM6 150MIC BLT
G1118765	DAFILON BK 10/0(0,2)30CM 2XDLM6S 200 BLT
G1118773	DAFILON BK 9/0(0,3)30CM 2XDLM6S 200M BLT
G1118781	DAFILON BK 10/0(0,2)15CM DLM6S 200MI BLT

## DECLARATION OF CONFORMITY

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Reference	Product Name / Description
G1118790	DAFILON BK 9/0(0,3) 15CM DLM6S 200MI BLT
G1118838	DAFILON BK 10/0(0,2) 30CM DLM5 150MI BLT
G1118854	DAFILON BK 8/0(0,4) 45CM DLM6S 200MI BLT
G1118862	DAFILON BK 10/0(0,2)30CM 2XDLM5 150M BLT
G1118870	DAFILON BK 8/0(0,4)30CM 2XDLM6 150MI BLT
G1118889	DAFILON BK 8/0 (0,4) 15CM DLM6 150MI BLT
G1110020	DAFILON BK 10/0(0,2)15CM DLM4 125MIC BLT
G1110055	DAFILON BLK 10/0(0,2)8CM SLM6 150MIC BLT
X1111140	DAFILON BK 9/0(0,3)15CM DRCM5 100MIC BLT
X1111434	DAFILON BLK 9/0(0,3)15CM DRM5 100MIC BLT
X1118080	DAFILON BLK 11/0(0,1)10CM DRM4 70MIC BLT
X1118137	DAFILON BK 9/0 (0,3) 10CM DRM4S 140M BLT
X1118170	DAFILON BLK 8/0(0,4)15CM DRM6 140MIC BLT
X1118625	DAFILON BK 10/0(0,2)15CM HLM6 150MIC BLT
X1118706	DAFILON BK 10/0(0,2)30CM 2XDLM6 150M BLT
X1111922	DAFILON BK 10/0(0,2)20CM 2XPLM5 150M BLT
X1117041	DAFILON BLK 10/0(0,2)15CM DRM3 50MIC BLT
X1118013	DAFILON BK 10/0(0,2)15CM DRM6 140MIC BLT
X1118048	DAFILON BLK 10/0(0,2)15CM DRCM3 100M BLT
X1118064	DAFILON BK 11/0 (0,1) 5CM DRM3 50MIC BLT
X1118099	DAFILON BLK 10/0(0,2)10CM DRM4 70MIC BLT
X1118110	DAFILON BK 10/0(0,2)15CM DRM5 100MI BLT
X1118161	DAFILON BLK 9/0(0,3)15CM DRM6 140MIC BLT
X1118420	DAFILON BK 9/0(0,3)13CM PRCM5 100MIC BLT
X1118579	DAFILON BK 8/0(0,4)15CM DLM6S 200MIC BLT
X1118609	DAFILON BK 10/0(0,2)30CM 2XHLM6 150M BLT
X1118617	DAFILON BK 9/0(0,3) 30CM HLM6 150MIC BLT
X1118641	DAFILON BK 10/0(0,2)30CM HLM6 150MIC BLT
X1118650	DAFILON BLK 9/0(0,3)30CM HLM6 150MIC BLT
X1118668	DAFILON BK 8/0(0,4) 5CM 2XDLM6 150MI BLT
X1118714	DAFILON BK 9/0(0,3)30CM 2XDLM6 150MI BLT
X1118722	DAFILON BK 10/0(0,2)15CM DLM6 150MIC BLT
X1118730	DAFILON BLK 9/0(0,3)15CM DLM6 150MIC BLT
X1118749	DAFILON BK 10/0(0,2)30CM DLM6 150MIC BLT

**DECLARATION OF CONFORMITY**  
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Reference	Product Name / Description
X1118757	DAFILON BK 9/0(0,3) 30CM DLM6 150MIC BLT
X1118765	DAFILON BK 10/0(0,2)30CM 2XDLM6S 200 BLT
X1118773	DAFILON BK 9/0(0,3)30CM 2XDLM6S 200M BLT
X1118838	DAFILON BK 10/0(0,2) 30CM DLM5 150MI BLT
X1118862	DAFILON BK 10/0(0,2)30CM 2XDLM5 150M BLT

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

Title: DoC\_Dafilon\_III 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: Monday, 30 May 2022, 10:01 W. Europe Daylight Time  
Meaning: Document signed as Author

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