

DECLARATION OF CONFORMITY

Product Category: Medical Devices for Antimicrobial Wound Dressings
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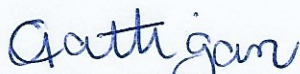
Product (Name, Type)	Date of CE marking	Previously
Askina® Calgitrol® Ag	08th May 2008	DoC 100, Revision 009
Askina® Calgitrol® THIN	10th September 2009	DoC 100, Revision 009
Askina® Calgitrol® Paste	08th May 2008	DoC 100, Revision 009

Article numbers: see attachment

Conformity Assessment Procedure	acc. to ANNEX II of the COUNCIL DIRECTIVE 93/42/EEC
Classification	according to ANNEX IX of the COUNCIL DIRECTIVE 93/42/EEC
Class / Rule	Class III / Rule 13
Applied Standards	EN ISO 13485:2016
CE Certificate	Certificate No. MD19.0173
EC Certificate	No. 252.727, all valid until 26 th June 2023
Notified Body	NSAI
Identification no.	0050

We herewith declare under our sole responsibility that the above mentioned products meet all the provisions of the COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993, which apply to them, as stated in ANNEX II

Issued by B. Braun Hospicare Ltd., Collooney, Co. Sligo on the 09th August 2021



Amelia Cattigan
Quality Manager



Seamus Kelly
MDR Project Manager

Effective



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Attachment for medical Devices Class III

Article number	Description	Size	Box Size
6211003	Askina [®] Calgitrol [®] Ag	10 x 10cm	3
6211010	Askina [®] Calgitrol [®] Ag	10 x 10cm	10
6211503	Askina [®] Calgitrol [®] Ag	15 x 15cm	3
6211510	Askina [®] Calgitrol [®] Ag	15 x 15cm	10
6212010	Askina [®] Calgitrol [®] Ag	20 x 20cm	10
6201010	Askina [®] Calgitrol [®] THIN	10 X 10 cm	10
6205510	Askina [®] Calgitrol [®] THIN	5 X 5 cm	10
6202110	Askina [®] Calgitrol [®] THIN	10 x 20 cm	10
6202010	Askina [®] Calgitrol [®] THIN	20 x 20 cm	10
6202403	Askina [®] Calgitrol [®] THIN	20 x 40 cm	3
6241505	Askina [®] Calgitrol [®] Paste	15 g	5
6241510	Askina [®] Calgitrol [®] Paste	15 g	10
6241001	Askina [®] Calgitrol [®] Paste	100 g	1

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