

DECLARATION OF CONFORMITY

Product Category: Soft silicone Dressing For Scar management

Product (Name, Type)	Date of CE marking	Previously
Askina® Scar Repair	NA	Doc No. 104 Rev 003

Article numbers: see attachment

Conformity Assessment Procedure	acc. to ANNEX VII of the COUNCIL DIRECTIVE 93/42/EEC
Classification	Class I (Non-Sterile)
Class / Rule	Class I (Non-Sterile), Rule 4
Applied Standards	EN ISO 13485:2016
CE Certificate	Certificate No. MD19.0173
EC Certificate	N/A
Notified Body	HPRA
Identification no.	N/A
Competent Authority	The Health Products Regulatory Authority (HPRA) have been appointed to supervise the provisions of Annex VII of the Medical Device Directive

The products covered by this current EC Declaration bear the CE marking according to MDD 93/42/EEC, and meet all applicable provisions and Essentials Requirements of the Medical Device Directive (transposed into Irish National Law per SI 252), which allows their free distribution, sale and circulation in the European Union.

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 VII.

Issued by B. Braun Hospicare Ltd., Collooney, Co. Sligo on the 22nd of July 2021

Amelia Cattigan

Amelia Cattigan
Quality Manager

22 JUL 21

Bogdan Militaru
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Jr. Manager Regulatory Affairs

22nd of July 2021

DECLARATION OF CONFORMITY**Attachment for medical Devices Class 1 (Non-sterile)**

Article number	Description	Size	Box Size
5695705	Askina® Scar repair	5 x 7.5cm	5
5691805	Askina® Scar repair	10 x 18cm	5
5694305	Askina® Scar repair	4 x 30cm	5
5691403	Askina® Scar repair	5 strips 2 x 14cm	3