



B. Braun Hospicare Limited
Collooney,
Co. Sligo,
Ireland.

DECLARATION OF CONFORMITY

Tel: + 353 71 9115000
Fax: + 353 71 9115064

Product Category: No Sting Protective Film

Product (Name, Type)	Date of CE marking	Previously
Askina® Barrier Film Spray	NA	Doc No. 108, 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 Certificate No. MD19.0173 Valid until 31 st July 2021
CE Certificate	NA
EC Certificates	No. Doc 108 Rev 004
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 19th August 2020


Mary Fowley
Senior Quality engineer


Hannah Hannant
Regulatory Affairs Specialist

The Board:

Dr. Marc Alexander Burmeister (Director Chairman)
Mr. Paul Mullaly (Director)
Mr. Pat McLoughlin (Director)
Ms. Christelle Garier-Reboul (Director)
Mr. Eric Samson (Director)
Mr. Mario Suarez (Director)

Registered in Ireland, No.: 96551
at above address

W.P. No. IE 12337546





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Attachment for medical Devices Class 1 (Non-sterile)

Article number	Description	Size	Box Size
4002801	Askina® Barrier Film Spray	28 ml	1

The Board:

Dr. Marc Alexander Burneister (Director Chairman)

Mr. Paul Muihaly (Director)

Mr. Pat McLoughlin (Director)

Ms. Christelle Garier-Reboul (Director)

Mr. Eric Samson (Director)

Mr. Niall Sweeney (Director)

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VENUE 00000000



MEDICAL
DEVICES
ISO 13485:2016
NSAI Certified