



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

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

DECLARATION OF CONFORMITY

Product Category: Medical Devices for Synthetic polymer semi-permeable film, adhesive, sterile Wound Dressings

Product (Name, Type)	Date of CE marking	Previously
Askina® Pad		Doc No. 102 Revision 004
Askina® Pad S	1 st May 2001	Doc No. 102 Revision 004
Askina® Soft		Doc No. 102 Revision 004
Askina® Soft IV	1 st May 2001	Doc No. 102 Revision 004
Askina® Soft Clear	18 th September 2001	Doc No. 102 Revision 004
Askina® Soft Clear IV	30 th May 2002	Doc No. 102 Revision 004
Askina® Trachea	6 th March 2008	Doc No. 102 Revision 004
Askina® Barrier Film Swab	11 th May 2010	Doc No. 102 Revision 004

Article numbers: see attachment

Conformity Assessment Procedure acc. to ANNEX V of the COUNCIL DIRECTIVE 93/42/EEC
Classification according to ANNEX IX of the COUNCIL DIRECTIVE 93/42/EEC
Class / Rule Class I Sterile per Rule 4
Applied Standards EN ISO 13485:2016 Certificate No. MD19.0173
 Valid until 31st July 2021
CE Certificate No. Q252.280, all valid until 26th May 2024
EC Certificates No. Doc 102 Rev 005
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 V.

Issued by B. Braun Hospicare Ltd., Collooney, Co. Sligo on the 19 August 2020

M. Fowley 19 Aug 20
Mary Fowley
 Senior Quality engineer

H. Hannant 19 Aug 20
Hannah Hannant
 Regulatory Affairs Specialist

The Board:
 Dr. Marc Alexander Burnmeister (Director Chairman)
 Mr. Paul Mullaly (Director)
 Mr. Pat McLoughlin (Director)
 Ms. Christelle Garier-Reboul (Director)
 Mr. Eric Sanson (Director)
 Mr. Martin Sweeney (Director)

Registered in Ireland, No.: 96551
 at above address





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Attachment for medical Devices Class 1 (sterile)

Article number	Description	Size	Box Size
9024000	Askina® Pad	5 x 5 cm	25
9024018	Askina® Pad	5 x 5 cm	100
9024026	Askina® Pad	10 x 10 cm	10
9024034	Askina® Pad	10 x 10 cm	100
9024042	Askina® Pad	10 x 20 cm	100
9024050	Askina® Pad S	5 x 5 cm	30
9024069	Askina® Pad S	7.5 x 7.5 cm	30
9086480	Askina® Soft	5 x 7.5 cm	50
9086501	Askina® Soft	9 x 5 cm	50
9086510	Askina® Soft	9 x 10 cm	50
9086515	Askina® Soft	9 x 15 cm	10
9086528	Askina® Soft	9 x 15 cm	40
9086536	Askina® Soft	9 x 20 cm	30
9086544	Askina® Soft	9 x 25 cm	30
9086552	Askina® Soft	9 x 30 cm	30
9086919	Askina® Soft IV	8 x 6 cm	50
9086803	Askina® Soft Clear	7.5 x 5 cm	50
9086812	Askina® Soft Clear	9 x 5 cm	50
9086821	Askina® Soft Clear	9 x 10 cm	50
9086830	Askina® Soft Clear	9 x 15 cm	40
9086839	Askina® Soft Clear	9 x 20 cm	30
9086848	Askina® Soft Clear	9 x 25 cm	30
9086857	Askina® Soft Clear	9 x 30 cm	30
9086893	Askina® Soft Clear IV	8 x 6 cm	50
7248510	Askina® Trachea	9.5 x 8.5 cm	10
4000105	Askina® Barrier Film Swab	1 ml	5
4000125	Askina® Barrier Film Swab	1 ml	25
4000305	Askina® Barrier Film Swab	3 ml	5
4000325	Askina® Barrier Film Swab	3 ml	25

The Board:

Dr. Marc Alexander Burmeister (Director Chairman)

Mr. Paul Mullaly (Director)

Mr. Pat McLoughlin (Director)

Ms. Christelle Garier-Reboui (Director)

Mr. Eric Samson (Director)

Mr. Neill Sweeney (Director)

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V.I.E. No. E 1727916