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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 005
Askina® Pad S	1st May 2001	Doc No. 102 Revision 005
Askina® Soft		Doc No. 102 Revision 005
Askina® Soft IV	1st May 2001	Doc No. 102 Revision 005
Askina® Soft Clear	18th September 2001	Doc No. 102 Revision 005
Askina® Soft Clear IV	30th May 2002	Doc No. 102 Revision 005
Askina® Trachea	6th March 2008	Doc No. 102 Revision 005
Askina® Barrier Film Swab	11th May 2010	Doc No. 102 Revision 005

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
CE Certificate	Certificate No. MD19.0173
EC Certificate	No. Q252.280, all valid until 26th May 2024
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 22nd of July 2021

Cattigan 22 JUL 21

22nd of July 2021

Amelia Cattigan
Quality Manager

Bogdan Militaru
Jr. Manager Regulatory Affairs

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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

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