

**DECLARATION OF CONFORMITY**

<b>Product Category: Medical Devices for Synthetic polymer semi-permeable film, adhesive, sterile Wound Dressings</b>
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Product (Name, Type)	Date of CE marking	Previously
Askina® Pad		Doc No. 102 Revision 005
Askina® Pad S	1 <sup>st</sup> May 2001	Doc No. 102 Revision 005
Askina® Soft		Doc No. 102 Revision 005
Askina® Soft IV	1 <sup>st</sup> May 2001	Doc No. 102 Revision 005
Askina® Soft Clear	18 <sup>th</sup> September 2001	Doc No. 102 Revision 005
Askina® Soft Clear IV	30 <sup>th</sup> May 2002	Doc No. 102 Revision 005
Askina® Trachea	6 <sup>th</sup> March 2008	Doc No. 102 Revision 005
Askina® Barrier Film Swab	11 <sup>th</sup> May 2010	Doc No. 102 Revision 005

Article numbers: see attachment

<b>Conformity Assessment Procedure</b>	acc. to ANNEX V of the COUNCIL DIRECTIVE 93/42/EEC
<b>Classification</b>	according to ANNEX IX of the COUNCIL DIRECTIVE 93/42/EEC
<b>Class / Rule</b>	Class I Sterile per Rule 4
<b>Applied Standards</b>	EN ISO 13485:2016
<b>CE Certificate</b>	Certificate No. MD19.0173
<b>EC Certificate</b>	No. Q252.280, all valid until 26 <sup>th</sup> May 2024
<b>Notified Body</b>	NSAI
<b>Identification no.</b>	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 22<sup>nd</sup> of July 2021

*Amelia Cattigan 22 Jul 21*

**Amelia Cattigan**  
Quality Manager



22<sup>nd</sup> of July 2021

**Bogdan Militaru**  
Jr. Manager Regulatory Affairs

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

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

**Effective**