

**DECLARATION OF CONFORMITY**

**Product Category: Medical Devices for sterile Wound Care Dressings (Exudate-absorbent dressing, non-gel & hydrophilic-gel, Wound hydrogel dressing, Odour-absorbent dressing, Wound-non adherent dressing, absorbent)**

Product (Name, Type)	Date of CE marking	Previously
Askina <sup>®</sup> Transorbent <sup>®</sup>	12th June 1998	DoC 103, Rev 010
Askina <sup>®</sup> Transorbent Sacrum <sup>®</sup>	13th March 2001	DoC 103, Rev 010
Askina <sup>®</sup> Transorbent Border <sup>®</sup>	12th June 1998	DoC 103, Rev 010
Askina <sup>®</sup> Carbosorb <sup>®</sup>	5th March 1998	DoC 103, Rev 010
Askina <sup>®</sup> Derm <sup>®</sup>	25th February 1999	DoC 103, Rev 010
Askina <sup>®</sup> Touch <sup>®</sup>	14th June 2002	DoC 103, Rev 010
Askina <sup>®</sup> Sorb <sup>®</sup>	28th February 2003	DoC 103, Rev 010
Askina <sup>®</sup> Sorb <sup>®</sup> Rope <sup>®</sup>		DoC 103, Rev 010
Askina <sup>®</sup> Heel <sup>®</sup>	18th November 2004	DoC 103, Rev 010
Askina <sup>®</sup> Foam <sup>®</sup>	18th May 2005	DoC 103, Rev 010
Askina <sup>®</sup> Foam Cavity <sup>®</sup>	24th November 2006	DoC 103, Rev 010
Askina <sup>®</sup> Foam Border <sup>®</sup>		DoC 103, Rev 010
Askina <sup>®</sup> Foam Sacrum <sup>®</sup>		DoC 103, Rev 010
Askina <sup>®</sup> Cavity Strips <sup>®</sup>	25th May 2007	DoC 103, Rev 010
Askina <sup>®</sup> SilNet <sup>®</sup>	3rd April 2009	DoC 103, Rev 010
Askina <sup>®</sup> DresSil <sup>®</sup>	8th June 2010	DoC 103, Rev 010
Askina <sup>®</sup> DresSil Border <sup>®</sup>	8th June 2010	DoC 103, Rev 010
Askina <sup>®</sup> DresSil Sacrum <sup>®</sup>	8th June 2010	DoC 103, Rev 010
Askina <sup>®</sup> DresSil Heel <sup>®</sup>	8th June 2010	DoC 103, Rev 010
Askina <sup>®</sup> Absorb + <sup>®</sup>	21st March 2012	DoC 103, Rev 010

Article numbers: see attachment

The Board:

Dr. Marc Alexander Burmeister (Director Chairman)  
Mr. Paul Mullaly (Director)  
Ms. Christèle Garier-Reboul (Director)  
Mr. Christoph Mueller (Director)





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

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<b>Conformity Assessment Procedure</b>	acc. to ANNEX II of the COUNCIL DIRECTIVE 93/42/EEC
<b>Classification</b>	according to ANNEX II of the COUNCIL DIRECTIVE 93/42/EEC
<b>Class / Rule</b>	Class IIA per Rule 4 (Askina <sup>®</sup> Carbosorb <sup>®</sup> , Askina <sup>®</sup> Derm <sup>®</sup> ) Class IIB per Rule 4
<b>Applied Standards</b>	EN ISO 13485:2016
<b>CE Certificate</b>	Certificate No. MD19.0173
<b>EC Certificate</b>	No. 252.314, all valid until 26 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 II.

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

*[Signature]*  
**Bogdan Militaru**  
Jr. Manager Regulatory Affairs

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

**Effective**

The Board:

Dr. Marc Alexander Burmeister (Director Chairman)  
Mr. Paul Mullaly (Director)  
Ms. Cristelle Greer-Reby (Director)  
Mr. Eric Samson (Director)  
Mr. Christoph Mueller (Director)







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## DECLARATION OF CONFORMITY

### Attachment for medical Devices Class IIA and IIB

Article number	Description	Size	Box Size
0072788T	Askina® Transorbent	10 x 10cm	10
0072789U	Askina® Transorbent	10 x 10cm	5
0072786R	Askina® Transorbent	5 x 7cm	10
0072790V	Askina® Transorbent	15 x 15cm	5
0072791W	Askina® Transorbent	20 x 20cm	5
0072783RES	Askina® Transorbent	5 x 7cm	3
0072793VES	Askina® Transorbent	15 x 15cm	3
0072794V	Askina® Transorbent	15 x 15cm	10
0072796W	Askina® Transorbent	20 x 20cm	10
0072799X	Askina® Transorbent Sacrum	18 x 20cm	10
0072799XFR	Askina® Transorbent Sacrum	18 x 20cm	10
0072795Z	Askina® Transorbent Sacrum	16 x 18	3
0072722Z	Askina® Transorbent Sacrum	20 x 22cm	10
0072792X	Askina® Transorbent Sacrum	18 x 20cm	5
0072705B	Askina® Transorbent Border	9 x 14cm	5
0072710C	Askina® Transorbent Border	14 x 14cm	5
0072715D	Askina® Transorbent Border	17 x 17cm	5
0072720ERU	Askina® Transorbent Border	24 x 24cm	5
0072706B	Askina® Transorbent Border	9 x 14cm	10
0072707B	Askina® Transorbent Border	9 x 14cm	3
0072707BES	Askina® Transorbent Border	9 x 14cm	3
0072712C	Askina® Transorbent Border	9 x 14cm	3
0072712CES	Askina® Transorbent Border	9 x 14cm	3
9025006	Askina® Carbosorb	10 x 10cm	10
9025014	Askina® Carbosorb	10 x 20cm	10
9025022	Askina® Carbosorb	10 x 10cm	3

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Mr. Paul Mullaly (Director)

Mr. Christel Carier-Redel (Director)

Mr. Eric Samson (Director)

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Article number	Description	Size	Box Size
9025022ES	Askina® Carbosorb	10 x 10cm	3
9025030	Askina® Carbosorb	10 x 20cm	3
9025030ES	Askina® Carbosorb	10 x 20cm	3
9025070	Askina® Carbosorb	10 x 10cm	12
9025070FR	Askina® Carbosorb	10 x 10cm	12
9025078	Askina® Carbosorb	10 x 20cm	12
9025078FR	Askina® Carbosorb	10 x 20cm	12
F72031	Askina® Derm	6 x 7cm	5
F72032	Askina® Derm	6 x 7cm	10
F72032FR	Askina® Derm	6 x 7cm	10
F72033	Askina® Derm	6 x 7cm	100
F72034	Askina® Derm	10 x 12cm	5
F72035	Askina® Derm	10 x 12cm	10
F72035FR	Askina® Derm	10 x 12cm	10
F72036	Askina® Derm	10 x 12cm	50
F72037	Askina® Derm	10 x 20cm	10
F72038	Askina® Derm	15 x 20cm	10
F72038FR	Askina® Derm	15 x 20cm	10
F72039	Askina® Derm	30 x 20cm	10
7261001	Askina® Touch	10 x 10cm	3
7261002	Askina® Touch	10 x 10cm	10
7261501	Askina® Touch	10 x 15cm	5
7262252	Askina® Touch	15 x 15cm	5
7262253	Askina® Touch	15 x 15cm	10
7264001	Askina® Touch	20 x 20cm	5
7261502	Askina® Touch	10 x 15cm	3
7261502ES	Askina® Touch	10 x 15cm	3
2100S	Askina® Sorb	6 x 6cm	15
2101S	Askina® Sorb	10 x 10cm	15
2102FR	Askina® Sorb	15 x 15cm	10
2102S	Askina® Sorb	15 x 15cm	10

**Effective**

The Board  
Dr. Marc Alexander Burnmeister (Director Chairman)  
Mr. Paul Mulaly (Director)  
Mr. Chris Garner (Director)  
Mr. Eric Samson (Director)  
Mr. Christoph Mueller (Director)







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Article number	Description	Size	Box Size
002105FR	Askina® Sorb	2.7 x 37cm	10
2107S	Askina® Sorb	10 x 10cm	3
2108SES	Askina® Sorb	15 x 15cm	3
2109S	Askina® Sorb	6 x 6cm	3
2115S	Askina® Sorb	6 x 6cm	10
2116S	Askina® Sorb	10 x 10cm	10
2116SFR	Askina® Sorb	10 x 10cm	10
2105S	Askina® Sorb Rope	2.7 x 34cm	10
2106S	Askina® Sorb Rope	2.7 x 34cm	3
7240103	Askina® Heel	N/A	3
7240105	Askina® Heel	N/A	5
7240110	Askina® Heel	N/A	10
7240110FR	Askina® Heel	N/A	10
7241003	Askina® Foam	10 x 10cm	3
7241010	Askina® Foam	10 x 10cm	10
7241010FR	Askina® Foam	10 x 10cm	10
7241510	Askina® Foam	15 x 20	10
7241510FR	Askina® Foam	15 x 20	10
7242005	Askina® Foam	20 x 20cm	5
7241210	Askina® Foam	10 x 20cm	10
7240703	Askina® Foam	5 x 7cm	3
7240710	Askina® Foam	5 x 7cm	10
7244003	Askina® Foam Cavity	2.5 x 40cm	3
7244010	Askina® Foam Cavity	2.5 x 40cm	10
7246010	Askina Cavity Strips	2.5 x 40cm	10
7246010FR	Askina Cavity Strips	2.5 x 40cm	10
5197510	Askina® SilNet	10 x 7.5cm	10
5191803	Askina® SilNet	10 x 18cm	3
5191810	Askina® SilNet	10 x 18cm	10
5192305	Askina® SilNet	20 x 30cm	5
5195703	Askina® SilNet	5 x 7.5cm	3

## The Board:

Dr. Marc Alexander Burmeister (Director Chairman)

Mr. Paul Mulaly (Director)

Mr. Niall O'Connell (Director)

Mr. Eric Samson (Director)

Mr. Christoph Mueller (Director)





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5195710	Askina® SilNet	5 x 7.5cm	10
5295703	Askina® DresSil	5 x 7cm	3
5295710	Askina® DresSil	5 x 7cm	10
5291003	Askina® DresSil	10 x 10cm	3
5291003ES	Askina® DresSil	10 x 10cm	3
5291005	Askina® DresSil	10 x 10cm	5
5291010	Askina® DresSil	10 x 10cm	10
5291010FR	Askina® DresSil	10 x 10cm	10
5291503	Askina® DresSil	15 x 15cm	3
5291505F	Askina® DresSil	15 x 15cm	5
5291510	Askina® DresSil	15 x 15cm	10
5291203	Askina® DresSil	10 x 20cm	3
5291205	Askina® DresSil	10 x 20cm	5
5291210	Askina® DresSil	10 x 20cm	10
5291210FR	Askina® DresSil	10 x 20cm	10
5292005	Askina® DresSil	20 x 20cm	5
5292010	Askina® DresSil	20 x 20cm	10
5292010FR	Askina® DresSil	20 x 20cm	10
5391003	Askina® DresSil Border	10 x 10cm	3
5391010	Askina® DresSil Border	10 x 10cm	10
5391010FR	Askina® DresSil Border	10 x 10cm	10
5391503	Askina® DresSil Border	15 x 15cm	3
5391510	Askina® DresSil Border	15 x 15cm	10
5392005	Askina® DresSil Border	20 x 20cm	5
5395203	Askina® DresSil Border	15 x 20cm	3
5395210	Askina® DresSil Border	15 x 20cm	10
5395210FR	Askina® DresSil Border	15 x 20cm	10
5397503	Askina® DresSil Border	7.5 x 7.5cm	3
5397510	Askina® DresSil Border	7.5 x 7.5cm	10
5397510FR	Askina® DresSil Border	7.5 x 7.5cm	10
5396610	Askina® DresSil Border	6 x 6cm	10

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5391210	Askina® DresSil Border	10 x 20cm	10
5391210FR	Askina® DresSil Border	10 x 20cm	10
5392010	Askina® DresSil Border	20 x 20cm	10
5392010FR	Askina® DresSil Border	20 x 20cm	10
5491605	Askina® DresSil Sacrum	16 x 17.5cm	5
5491610	Askina® DresSil Sacrum	16 x 17.5cm	10
5491610FR	Askina® DresSil Sacrum	16 x 17.5cm	10
5492110	Askina® DresSil Sacrum	21 x 22cm	10
5492105	Askina® DresSil Sacrum	21 x 22cm	5
5592205	Askina® DresSil Heel	22 x 21.6cm	5
5592210	Askina® DresSil Heel	22 x 21.6cm	10
5592210FR	Askina® DresSil Heel	22 x 21.6cm	10
3331010	Askina® Absorb +	10 x 10cm	10
3331210	Askina® Absorb +	10 x 20cm	10
3332005	Askina® Absorb +	20 x 20cm	5

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