



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

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

DECLARATION OF CONFORMITY

Product Category: Sting Free Medical Adhesive Remover

Product (Name, Type)	Date of CE marking	Previously
B. Braun Adhesive Remover	NA	Doc No. 107 Revision 002

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 31st July 2021
CE Certificate NA
EC Certificates No. Doc 107, Rev 003
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 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 Burmeister (Director Chairman)
 Mr. Paul Mullaly (Director)
 Mr. Pat McLoughlin (Director)
 Ms. Christelle Garier-Reboul (Director)
 Mr. Eric Sanson (Director)
 Mr. John Sweeney (Director)

Registered in Ireland, No.: 96551
 at above address





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Attachment for medical Devices Class 1 (Non-sterile)

Article number	Description	Size	Box Size
AR5001	B. Braun adhesive Remover	50 ml	1

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. Martin Sweeney (Director)

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VAT No. IE 47327646

Effective

