



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

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

DECLARATION OF CONFORMITY

Product Category: Protective Skin barrier Paste		
Product (Name, Type)	Date of CE marking	Previously
Superfiller	NA	Doc No. 106, Rev 002

Article numbers: see attachment

Conformity Assessment Procedure	acc. to ANNEX VII of the COUNCIL DIRECTIVE 93/42/EEC
Classification	Class 1 (Non-Sterile)
Class / Rule	Class I (Non-Sterile), Rule 4
Applied Standards	EN ISO 13485:2016 Certificate No. MD19.0173 Valid until 31 st July 2021
CE Certificate	NA
EC Certificates	No. Doc 106 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 19th August 2020.


Mary Fowley
Senior Quality engineer


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 Samson (Director)
Mr. Mario Sovera (Director)

Registered in Ireland, No.: 96551
at above address

WAT No. IE 12327646





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Attachment for medical Devices Class 1 (Non-sterile)

Article number	Description	Size	Box Size
F05008	Superfiller	60g	1

The Board:

Dr. Marc Alexander Bumeister (Director Chairman)

Mr. Paul Mullaly (Director)

Mr. Pat McLoughlin (Director)

Ms. Christelle Garier-Reboul (Director)

Mr. Eric Samson (Director)

Mr. Martin Sweeney (Director)

Registered in Ireland, No: 96551
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VAT No: IE 47337646

