Document Number: DOC 023 - Superfiller

Revision 007
Updated signatory

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B BRAUN

Declaration of Conformity

B. Braun Hospicare Limited
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M.S.D.N: 0100114064 - C.T.T.N.H.H - CÔNG TY TRÁCH NHIỆM HỮU HẠN B.BRAUN VIỆT NAM - H. HOÀI ĐỨC - TP. HÀ NỘI

Manufacturer:	B. Braun Hospicare Ltd.
Address :	Collooney Co. Sligo Ireland
Product :	Superfiller
Ref:	F05008
Classification :	I (Non-Sterile)
Scope :	B.Braun Hospicare Ltd. declares that the above mentioned product conforms to the requirements of the Medical Device Directive 93/42/EEC under Conformity Assessment Route annex II (Amended to 2007/47/EC).
Competent Authority	The Health Products Regulatory Authority (HPRA) have been appointed to supervise the provisions of Annex VII of 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.

Document No.	Title	Edition/Date of Issue
L169	Council Directive 93/42/EEC concerning Medical Devices.	14/06/1993

Additional Information :

Superfiller is registered as a Class I (Non-Sterile) medical deivice with the Competent Authority, Health Products Regulatory Authority (HPRA)

The manufacturer B. Braun Hospicare Ltd. is registered to I.S. EN ISO 13485 : 2012. under Registration No. MD 19.0173, issued by NSAI on 25/03/1995, valid until 31/07/2017.

Issued on this 15 day of June 2017 by Joanne Scanlon Senior Quality Engineer

Joanne Scanlon (Senior Quality Engineer)

The Board:
Dr. Marc Alexander Burmeister (Director Chairman)
Mr. Paul Mullaly (Director)
Ms. Christelle Garier-Reboul (Director)
Mr. Eric Samson (Director)
Mr. Christoph Mueller (Director)

Registered in Ireland, No.: 96551
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MEDICAL DEVICES
ISO 13485:2012
NSAI Certified