

EU DECLARATION OF CONFORMITY

Manufacturer: **KARABINIS MEDICAL SA**
151 Lavriou av. 19002, PAIANIA, ATTICA, GREECE.
Tel. 0030-210-6645751, fax. 0030-210-6646000,
info@karabinismedical.gr

Product(s): Sterile Gauze with Steam

Brand name(s): Alfashield

Intended purpose: Medical dressing used as mechanical barrier, for compression or for absorption of exudates or to manage the micro-environment of a wound

Classification & rule: Class IIa, rule 4 according to Annex IX of MDD 93/42/EEC

Conformity assessment route: Annex V of MDD 93/42

Notified body: EKAPTY

Identification number: 0653

EC Certificate number: 302081031M

Certificate expiry date: 24/07/2023

Karabinis Medical SA declares under its sole responsibility that the product(s) stated above and in ANNEX below are manufactured in accordance to Annex VII and conform to the Council Directive 93/42/EEC relating to Medical Devices.

For and on behalf of Karabinis Medical SA,

Signature

Mr. Apostolos Karabinis
Title: Founder, President &
Managing Director

KARABINIS MEDICAL S.A.

Manufacturing & Sales of Medical Devices - Health Services

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Athens, 08.09.2021

Place and date

