



EC DECLARATION OF CONFORMITY

IN RELATION TO HYDRO-ALGINATE ANTIMICROBIAL WOUND DRESSING WITH SILVER (DESIGN DOSSIER 01)

Advanced Medical Solutions Ltd. (Premier Park, 33 Road One, Winsford Industrial Estate, Winsford, Cheshire, CW7 3RT, United Kingdom) declares that the Class III medical devices manufactured by Advanced Medical Solutions and described hereafter as:

Product Name	Size (cm)	Catalogue Number [REF]
SILVERCEL® Non-Adherent Hydro-Alginate Antimicrobial Dressing with Silver	5 x 5	CAD7050#
	11 x 11	CAD7011#
	10 x 20	CAD7020#
SILVERCEL® Non-Adherent Hydro-Alginate Antimicrobial Packing with Silver	2.5 x 30.5	CAD7230#
RELEASE® Ag Non-Adherent Hydro-Alginate Antimicrobial Dressing with Silver	11 x 11	DAC711FH
	10 x 20	DAC720FH
SILVERCEL® Hydro-Alginate Antimicrobial Dressing with Silver	5 x 5	CAD050#
	11 x 11	CAD011#
	10 x 20	CAD020#
SILVERCEL® Hydro-Alginate Antimicrobial Packing with Silver	2.5 x 30.5	CAD230#

indicates a product code may be followed by a suffix for a market-specific product coding

GMDN Code: 47474 – Exudate-absorbent dressing, hydrophilic-gel, antimicrobial, sterile

are in conformity with the essential requirements and provisions of Council Directive 93/42/EEC (Medical Devices Directive) amended by Directive 2007/47/EC, as transposed into UK Regulations (Statutory Instrument 2002 No. 618 and Statutory Instrument 2012 No. 1426) subject to and in conformity with the applicable provisions of Annex II, Full Quality Assurance Certificate (CE 01699) and EC Design Examination certificate (CE 70851), under the supervision of our Notified Body the British Standards Institution (2797).

Authorised Representative Advanced Medical Solutions B.V., Munnikenheiweg 35, 4879 NE
Etten-Leur, Netherlands.

Standards Applied: Refer to referenced Design Dossier.



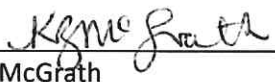


Advanced Medical Solutions Ltd

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DD01-003, Rev.11

Issued in Winsford, UK.



Kay McGrath
Regulatory Affairs Manager

23 March 2021
Date

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Certificate No. MD78010