



Advanced Medical Solutions Ltd

Advanced Medical Solutions Limited
Premier Park, 33 Road One
Winsford Industrial Estate
Cheshire. CW7 3RT. UK

DD02-001, Rev 09

EC DECLARATION OF CONFORMITY
IN RELATION TO SILVER ALGINATE II ANTIMICROBIAL WOUND DRESSING
DESIGN DOSSIER 02

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]
Biatain Alginate Ag	5 x 5	3755
	10 x 10	3760
	15 x 15	3765
	3 x 44	3780
	30 x 20	3790

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

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. 1425) subject to and in conformity with the applicable provisions of Annex II, Full Quality Assurance Certificate (CE01699) and EC Design Examination certificate (CE97750), 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 the relevant section of Design Dossier 02 (DD02)

Issued in Winsford, UK.


Adam Gregory
Regulatory Affairs Manager

12 MAY 2020

Date

Doc reference: DD02 - Silver Alginate II Antimicrobial Wound Dressing, Revision 03, Issue Date: Apr-2019



Certificate No. MD78010