



Advanced Medical Solutions Ltd

Advanced Medical Solutions Limited
Premier Park, 33 Road One,
Winsford Industrial Estate,
Winsford, Cheshire, CW7 3RT, UK
Tel: +44 (0) 1606 863500 Fax: +44 (0) 1606 863600
Web: www.admedsol.com
Registered in England 2666957 VAT No. GB 636 5551 27

DD02-010, Rev. 01 **DRAFT**

Addendum to: DD02-003, Rev. 06, dated 24-March 2021

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;

Coloplast Product Name	Size (cm)	Catalogue Number [REF]
alginür® Ag Silver Alginate Antimicrobial Wound Dressing	10 x 10	3010
	15 x 15	3011
	20 x 30	3012

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).

This EU declaration of conformity is issued under the sole responsibility of Advanced Medical Solutions Ltd.

The changes made comply with the transitional provisions of (EU) 2017/745 Article 120, such that the (EU) Declaration of Conformity (DD02-003, dated 24-March 2021) has not been invalidated.

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.

Unsigned Draft

Kay McGrath
Regulatory Affairs Manager

Date

Doc reference: DD02 - Silver Alginate II Antimicrobial Wound Dressing, Revision 04, Issue Date: January 2023.



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TF-B-010, Rev. 14

Addendum to: TF-B-010, Rev. 11, dated 22-December 2020

EC DECLARATION OF CONFORMITY IN RELATION TO FOAM DRESSINGS

This Declaration of Conformity is for the AMS generic products, which are defined using their internal AMS product names and/or codes as shown in the table below (therefore there are no Catalogue Numbers). Following issue of this Declaration of Conformity, subsequent Declarations of Conformity will be issued prior to placing the device on the market for the corresponding AMS branded and private label product variants.

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

Size (cm)	Foam Heel Dressing	Bilaminate Non- adhesive Foam	Bilaminate Adhesive Foam Dressing	Trilaminate Non- Adhesive Foam	Silicone Adhesive Border Foam	Silicone Adhesive Non- border Foam
Sacral, 18 x 18.5					✓	
Fenestrated, 10 x 10		✓		✓		
Heel shaped, 18 x 12	✓					
5 x 5		✓		✓		✓
7.5 x 7.5		✓	✓	✓	✓	✓
10 x 10		✓	✓	✓	✓	✓
12.5 x 12.5			✓	✓	✓	
15 x 15		✓	✓	✓	✓	✓
10 x 18		✓				
10 x 20		✓		✓	✓	✓
20 x 20		✓	✓	✓	✓	✓

- GMDN Code: 44970 – Exudate-absorbent dressing, non-gel

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 (CE01699), under the supervision of our Notified Body, the British Standards Institution (2797).

This EU declaration of conformity is issued under the sole responsibility of Advanced Medical Solutions Ltd.

The changes made comply with the transitional provisions of (EU) 2017/745 Article 120, such that the (EU) Declaration of Conformity (TF-B-010, dated 22-December 2020) has not been invalidated.

Authorised Representative: Advanced Medical Solutions B.V., Munnikenheiweg 35, 4879 NE
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TF-B-010, Rev. 14

Addendum to: TF-B-010, Rev. 11, dated 22-December 2020

Standards Applied: Refer to the relevant section of Technical File B (TF-B)

Issued in Winsford, UK.

DocuSigned by Kay McGrath
 I approve this document
20-Mar-2024 | 15:59 GMT
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20-Mar-2024 | 16:01 GMT

Kay McGrath

Date

Regulatory Affairs Manager

Doc reference: TF-B - Foam Dressings family Technical File, Rev 15, Issue Date: March 2024.