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

DD03-001, Rev 05
Addendum to: DD03-001, Rev. 4 dated 24 Mar 2021

EC DECLARATION OF CONFORMITY

IN RELATION TO SILVER ALGINATE IV ANTIMICROBIAL WOUND DRESSING (DESIGN DOSSIER 03)

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 III medical devices manufactured by Advanced Medical Solutions and described hereafter as listed below:

Product Name	Size
Silver Alginate IV Antimicrobial Wound Dressing	5cm x 5cm (2" x 2")
	10cm x 10cm (4" x 4")
	10cm x 12cm (4" x 4.75")
	15cm x 15cm (6" x 6")
	20cm x 30cm (8" x 12")
	2.7cm x 32cm (1" x 12.6")

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. 1426) subject to and in conformity with the applicable provisions of Annex II, Full Quality Assurance Certificate (CE01699) and EC Design Examination certificate (CE608297), under the supervision of our Notified Body the British Standards Institution (2797).

The (EU) Declaration of Conformity is issued under the sole responsibility of Advanced Medical Solutions.

The changes made comply with the transitional provisions of (EU) 2017/745 Article 120, such that the (EU) Declaration of Conformity (DD03-001 Rev 4, dated 24March 2021) has not been invalidated.

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

Standards Applied: Refer to Design Dossier DD03

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DD03-001, Rev 05

Addendum to: DD03-001, Rev. 4 dated 24 Mar 2021

Issued in Winsford, UK.

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26-Jan-2024 | 13:28 GMT

Kay McGrath

Regulatory Affairs Manager

Date

Doc reference: Design Dossier 3 for Silver Alginate IV Antimicrobial Wound Dressing – DD03 revision 5, Issue Date: January 2024.

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DD03-006, Rev 07
Addendum to: DD03-006, Rev. 6 dated 24 Mar 2021

EC DECLARATION OF CONFORMITY

IN RELATION TO SILVER ALGINATE IV ANTIMICROBIAL WOUND DRESSING (DESIGN DOSSIER 03)

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 listed below:

Product Name	Product Size (cm)	Catalogue Number [REF]
ActivHeal® Aquafiber Ag	5 x 5	9023236
	10 x 10	9023243
	10 x 12	9025476
	15 x 15	9023267
	20 x 30	9023274
	2.7 x 32	9023281

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. 1426) subject to and in conformity with the applicable provisions of Annex II, Full Quality Assurance Certificate (CE01699) and EC Design Examination certificate (CE608297), under the supervision of our Notified Body the British Standards Institution (2797).

The (EU) Declaration of Conformity is issued under the sole responsibility of Advanced Medical Solutions.

The changes made comply with the transitional provisions of (EU) 2017/745 Article 120, such that the (EU) Declaration of Conformity (DD03-006 Rev 6, 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 Design Dossier 03 (DD03).

Issued in Winsford, UK.

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Kay McGrath | I approve this document 26-Jan-2024 | 13:28 GMT
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Regulatory Affairs Manager

Date

Doc reference: Design Dossier 3 for Silver Alginate IV Antimicrobial Wound Dressings – DD03 revision 5, Issue Date: January 2024.

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CUSTOMER	AMS generic product Name	SIZE (cm)	Dressing Item code	Declaration of Conformity & STATUS	MDD 93/42 EEC STATUS	MDR (EU) 2017/745 STATUS
N/A – AMS generic product	Silver Alginate IV Antimicrobial Wound Dressing	5 x 5	10010874	**MDR DoC** EDC-010-001 Rev 1 DRAFT 2 DRAFT (unsigned) **MDD DoC** DD03-001 Rev 5 CERTIFIED (signed)	APPROVED Certificate CE 01699	Not yet approved
		10 x 10	10010875			
		10 x 12	10012009			
		15 x 15	10010876			
		20 x 30	10013592			
		2.7 x 32	10010877			
	BRAND NAME		**Catalogue Number [REF]**			
Medicline	nürocel®Ag Antimicrobial Dressing	5 x 5	8002	**MDD DoC** DD03-008 Rev 1 DRAFT 1 (unsigned)	CE marked	N/A – product not yet approved
		10 x 10	8003			
		15 x 15	8004			
		20 x 30	8005			

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		2.7 x 32	8001			
ActivHeal (AMS branded)	ActivHeal® Aquafiber Ag	5 x 5	9023236	**MDR DoC** EDC-010-002 Rev 1 DRAFT 2 DRAFT (unsigned) **MDD DoC** DD03-006 Rev 7 CERTIFIED (signed)	CE marked	N/A – product not yet approved
		10 x 10	9023243			
		10 x 12	9025476			
		15 x 15	9023267			
		20 x 30	9023274			
		2.7 x 32	9023281			

The table below shows the Medicline product (soon to be CE marked to MDR) and its equivalent (MDD) CE marked AMS branded ActivHeal product.

Customer: MEDICLINE		Size (cm)	Customer: ACTIVHEAL (AMS Branded)	
BRAND NAME	**Catalogue Number [REF]**		**Dressing Item Code**	**BRAND NAME**
nürocel®Ag Antimicrobial Dressing	8002	5 x 5	9023236	ActivHeal® Aquafiber Ag
	8003	10 x 10	9023243	
	8004	15 x 15	9023267	
	8005	20 x 30	9023274	

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	8001	2.7 x 32	9023281	

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8th May 2024

Medicline launch of AMS Dressings in Croatia

In relation to the additional requirements for registration and launch of Medicline products in EU member state, Croatia, AMS are providing the following information:

The tables provided on the following pages provide details, for each product category, of the EU MDD and MDR approval status, the complete range of the AMS generic product, the planned Medicline launch dressing sizes and catalogue numbers, and the AMS branded (ActivHeal) dressing sizes and catalogue numbers.

The EU declarations of conformity referenced in the tables are included as numbered attachments in the PDF file.

For each product category, the second table shows the Medicline product sizes and catalogue numbers (soon to be CE marked to MDD or MDR as appropriate) alongside their equivalent CE marked AMS branded ActivHeal products (CE marked to MDD or MDR or both). Please note; the only difference between the Medicline and ActivHeal product is the labelling (e.g. brand name, brand logo, languages present).

In some cases (such as Silicone Foam, HPD/41-2AP, Silicone Wound Contact Layer and Alginate), the Medicline launch will be of MDR product, whereas the AMS branded Activheal product has not yet been launched under MDR and is still CE marked under MDD only. In these cases, details of the ActivHeal MDD product are provided along with the approved ActivHeal MDD declaration of conformity and the draft (unsigned) MDR declaration of conformity.

Signed on behalf of Advanced Medical Solutions Limited

Nathan Wright
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AEO UK Authorised Economic Operator
bsi UKAS Certificate No. MD 78010