



Advanced Medical Solutions Ltd

Advanced Medical Solutions Limited
Premier Park, 33 Road One,
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Web: www.admedsol.com
Registered in England 2666957 VAT No. GB 636 5551 27

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
Regulatory Affairs Associate
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TF-A-004, Rev. 18

Addendum to:TF-A-004, Rev.11, dated 21 Aug 2020

EC DECLARATION OF CONFORMITY IN RELATION TO ACTIVHEAL® ALGinate, ACTIVHEAL AQUAFIBER® & ACTIVHEAL® AQUAFIBER EXTRA

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:

Product Name	Size	REF Code
ActivHeal® Alginate	5 x 5cm	10007432
	10 x 10cm	10007431
	10 x 12cm	9025452
	10 x 20cm	10007430
ActivHeal® Alginate Rope	30cm	10007428
ActivHeal Aquafiber®	5 x 5cm	10009145
	10 x 10cm	10009146
	10 x 12cm	9025469
	15 x 15cm	10009147
	2 x 46cm Ribbon	10009148
ActivHeal Aquafiber®Extra	5 x 5cm	9023625
	10 x 10cm	9023632
	10 x 12cm	9025483
	15 x 15cm	9023649
	20 x 30cm	9023656
	2.5 x 30.5cm Ribbon	9023663
	2 x 46cm Ribbon	9023670

GMDN Code-43186 - Exudate-absorbent dressing, hydrophilic-gel

are in conformity with the essential requirements and provisions of Council Directive 93/42/EEC (Medical Devices Directive), 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).

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



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TF-A-004, Rev. 18

Addendum to:TF-A-004, Rev.11, dated 21 Aug 2020

The changes made comply with the transitional provisions of (EU) 2017/745 Article 120, such that the (EU) Declaration of Conformity (TF-A-004 dated 21 Aug 2020) 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 Technical File A (TF-A).

Issued in Winsford, UK.

Digitally signed by Kay McGrath
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27-Nov-2023 | 11:39 GMT

Kay McGrath

Date

Regulatory Affairs Manager

Doc reference: Technical File A - Non-woven Dressings – TF-A Revision 13, Issue Date: May 2023



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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	Alginate (1-21A)	5 x 5	10009223	MDR DoC EDC-016-001 Rev 2 CERTIFIED (signed)	APPROVED Certificate CE 01699	APPROVED Certificate MDR 729334
		10 x 10	10009224			
		10 x 12	10009510			
		10 x 20	10009225			
		30cm Fluffy Rope	10002154	MDD DoC DoC_TF-A-001 Rev 16 CERTIFIED (signed)		
	BRAND NAME		Catalogue Number [REF]			
Medicline	alginür® Alginate Dressing	5 x 5	1002	MDR DoC EDC-016-004 Rev 1, DRAFT 1 (unsigned)	N/A – Medicline will launch MDR product	Not yet CE marked DoC in draft
		10 x 10	1003			
		10 x 20	1004			
		30cm Fluffy Rope	1001			
ActivHeal (AMS branded)	ActivHeal® Alginate	5 x 5	10007432	MDD DoC DoC_TF-A-004 Rev 18 CERTIFIED (signed)	CE marked	Not yet CE marked
		10 x 10	10007431			
		10 x 12	9025452			
		10 x 20	10007430			



Registered Office: Premier Park, 33 Road One, Winsford Industrial Estate, Winsford, Cheshire, CW7 3RT, UK

Certificate No. MD 78010



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		30cm fluffy rope	10007428	MDR DoC EDC-016-002 Rev 1 Draft 3 DRAFT (unsigned)	
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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		Customer: ACTIVHEAL (AMS Branded)	
BRAND NAME	Catalogue Number [REF]	Size (cm)	Dressing Item Code
alginür® Alginate Dressing	1002	5 x 5	10007432
	1003	10 x 10	10007431
	1004	10 x 20	10007430
	1001	2.5 x 30	10007428
		ActivHeal® Alginate	



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TF-A-001, Rev. 16

Addendum to:TF-A-001, Rev.10, dated 26 Nov 2020

EC DECLARATION OF CONFORMITY IN RELATION TO Non-woven 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 and described hereafter as:

Size cm	14-2A	14-2AP	1-21A	1-2B	1-21DP Reinforced	41-2AP (Reinforced)
5 x 5	✓	✓	✓	✓	✓	✓
6 x 6	✓					
10 x 10	✓	✓	✓	✓	✓	✓
10 x 12			✓		✓	✓
12.5 x 12.5					✓	
15 x 15	✓	✓			✓	✓
20 x 20						✓
20 x 30						✓
10 x 20	✓	✓	✓	✓	✓	✓
Flat Ropes						
2 x 46					✓	✓
2.5 x 42					✓	
2.5 x 30.5						✓
2.5 x 30			✓			
2.7 x 37	✓					
2.7 x 34	✓	✓				
3 x 44		✓				
Fluffy Ropes						
30cm	✓		✓	✓		



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TF-A-001, Rev. 16

Addendum to:TF-A-001, Rev.10, dated 26 Nov 2020

GMDN Code-43186 - Exudate-absorbent dressing, hydrophilic-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).

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 (TF-A-001 dated 26 Nov 2020) 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 Technical File A (TF-A).

Issued in Winsford, UK.

Doc signed by Kay McGrath

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Kay McGrath

Regulatory Affairs Manager

27-Nov-2023 | 11:39 GMT

Date

Doc reference: Technical File A - Non-woven Dressings Product Family – TF-A Revision 13, Issue Date: May 2023



EU Declaration of Conformity Regulation (EU) 2017/745 on Medical Devices

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.

We, the manufacturer:

Name	Advanced Medical Solutions Limited
Address	Premier Park, 33 Road One Winsford Industrial Estate Winsford Cheshire CW7 3RT UK
Single Registration Number	GB-MF-000008822

under our sole responsibility, certify that the products described below are in conformance with the applicable provisions of Regulation (EU) 2017/745 on medical devices:

Device Family	Alginate Non-woven Dressings
Intended Purpose:	Alginate Non-woven Dressings are intended to absorb wound exudate to form a gel that aids autolytic debridement (removal of non-viable tissue from the wound), whilst maintaining a moist wound environment to assist in the healing process of chronic and acute wounds.
Classification Rule Under Annex VIII:	Class IIb, under Rule 4 (2 nd indent)
Certification:	MDR 729334 (EU Quality Management System Certificate, Regulation (EU) 2017/745, Annex IX Chapter I and III)
Common specification:	Not applicable

AMS Product Name	Size (cm)	BASIC UDI-DI
1-21A Alginate Dressing	5 x 5	50327491810103KQ
	10 x 10	
	10 x 12	
	10 x 20	
	2.5 x 30	
	30cm fluffy rope	



AMS Product Name	Size (cm)	BASIC UDI-DI
1-21DP Reinforced Alginate Dressing	5 x 5	50327491810103KQ
	10 x 10	
	10 x 12	
	12.5 x 12.5	
	15 x 15	
	10 x 20	
	2.5 x 42	
	2 x 46	
1-2B Alginate Dressing	5 x 5	50327491810103KQ
	10 x 10	
	10 x 20	
	30cm fluffy rope	

The following Authorised Representative acts on behalf of the manufacturer:

Name	Advanced Medical Solutions B.V.
Address	Munnikenheiweg 35 4879 NE Etten-Leur The Netherlands
Single Registration Number	NL-AR-000000440

The devices listed above have undergone conformity assessment by BSI Group, The Netherlands B.V. (ID number 2797) in accordance with the requirements of Annex IX.

The following signatory is provided for and on behalf of Advanced Medical Solutions Ltd.

Kay McGrath

26 May 2023

Name Kay McGrath
Position Regulatory Affairs Manager
Place of issuance Advanced Medical Solutions Ltd.

Date

Doc reference: RTD-016 - Alginate Non-woven Dressings Regulatory Technical Documentation, Rev 5, Issue Date: May 2023.