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

TF-B-015, Rev 18
Addendum to: TF-B-015, Rev.13, dated 22-December 2020

EC DECLARATION OF CONFORMITY
IN RELATION TO ACTIVHEAL® FOAM DRESSINGS

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 / Catalogue Number
ActivHeal® Foam Adhesive	7.5cm x 7.5cm	10010232
	10cm x 10cm	10009109
	12.5cm x 12.5cm	10009110
	15 x 15cm	10010781
	20cm x 20cm	10009112
ActivHeal® Non-Adhesive Foam	5cm x 5cm	10009113
	7.5cm x 7.5cm	10009114
	10cm x 10cm	10009115
	15 x 15cm	10010781
	10cm x 20cm	10011265
	20cm x 20cm	10009117
ActivHeal® Tracheostomy Foam Non-Adhesive	10cm x 10cm	10009118
ActivHeal® Foam Heel Non-Adhesive	Heel	10010227
ActivHeal® Silicone Border Foam	7.5cm x 7.5cm	9001470
	10cm x 10cm	9001487
	10cm x 20cm	9001500
	12.5cm x 12.5cm	9001494
	15cm x 15cm	9001517
	20cm x 20cm	9001524
	18cm x 18.5cm, Sacral	9001531
ActivHeal® Silicone Non- Border Foam	5cm x 5cm	9001548
	7.5cm x 7.5cm	9001555
	10cm x 10cm	9001562
	10cm x 20cm	9001579
	15cm x 15cm	9001449
	20cm x 20cm	9001586

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

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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-015, dated 22-December 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 B (TF-B).

Issued in Winsford, UK.

DocuSigned by Kay McGrath
Kay McGrath | I approve this document 20-Mar-2024 | 15:59 GMT
CB71E53CE2D74B36BFAADF820C7B2DC0

20-Mar-2024 | 16:01 GMT

Kay McGrath

Date

Regulatory Affairs Manager

Doc reference: Technical File B for Foams Dressings – TF-B, Revision 15, Issue Date: March 2024.

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

Customer: MEDICLINE		Size (cm)	Customer: ACTIVHEAL (AMS Branded)	
BRAND NAME	**Catalogue Number [REF]**		**Dressing Item Code**	**BRAND NAME**
nürofoam® Sensitive Silicone Border Foam Dressing	6010	10 x 10	9001487	ActivHeal® Silicone Adhesive Foam Border
	6008	12.5 x 12.5	9001494	
	6009	10 x 20	9001500	
	6011	15 x 15	9001517	
	6012	20 x 20	9001524	
	6013	18 x 18.5, sacral	9001531	
nürofoam® Sensitive Silicone Non-Border Foam Dressing	6005	10 x 10	9001562	ActivHeal Silicone Non-border Foam
	6006	15 x 15	9001449	
	6007	10 x 20	9001579	

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	6014	20 x 20	9001586	

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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	Silicone Trilaminate Foam Border Dressing	7.5 x 7.5	10014949	**MDR DoC** EDC-008-001 Rev 2 CERTIFIED (signed) **MDD DoC** DoC_TF-B-010 Rev 14 CERTIFIED (signed)	APPROVED Certificate CE 01699	APPROVED Certificate MDR 729334
		10 x 10	10014950			
		10 x 20	10014951			
		12.5 x 12.5	10014952			
		15 x 15	10014953			
		20 x 20	10014954			
		18 x 18.5, sacral	10012135			
	Silicone Trilaminate Foam Non-border Dressing	5 x 5	10012136			
		7.5 x 7.5	10012137			
		10 x 10	10012138			
		10 x 20	10012139			
		15 x 15	10012140			
		20 x 20	10012141			

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	BRAND NAME		Catalogue Number [REF]			
Medicline	nürofoam® Sensitive Silicone Border Foam Dressing	10 x 10	6010	**MDR DoC** EDC-008-006 Rev 3, DRAFT (unsigned)	N/A – Medicline will launch MDR product	Not yet CE marked DoC in draft
		12.5 x 12.5	6008			
		10 x 20	6009			
		15 x 15	6011			
		20 x 20	6012			
		18 x 18.5, sacral	6013			
	nürofoam® Sensitive Silicone Non-Border Foam Dressing	10 x 10	6005			
		15 x 15	6006			
		10 x 20	6007			
		20 x 20	6014			
ActivHeal (AMS branded)	ActivHeal® Silicone Adhesive Foam Border	7.5 x 7.5	9001470		CE marked	CE marked
		10 x 10	9001487			
		10 x 20	9001500			
		12.5 x 12.5	9001494			
		15 x 15	9001517			

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		20 x 20	9001524	**MDR DoC** EDC-008-002 Rev 1 CERTIFIED (signed) **MDD DoC** DoC_TF-B-015 Rev 18 CERTIFIED (signed)		
		18 x 18.5, sacral	9001531			
	ActivHeal Silicone Non-border Foam	5 x 5	9001548	**MDR DoC** EDC-008-002 Rev 2 DRAFT (unsigned) **MDD DoC** DoC_TF-B-015 Rev 18 CERTIFIED (signed)	CE marked	Not yet CE marked
		7.5 x 7.5	9001555			
		10 x 10	9001562			
		10 x 20	9001579			
		15 x 15	9001449			
		20 x 20	9001586			

Advanced Medical Solutions Ltd
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Advanced Medical Solutions Ltd

TF-F –001, rev 07

EC DECLARATION OF CONFORMITY

IN RELATION TO SILICONE WOUND CONTACT LAYER DRESSING

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

Product Name	Size (cm)
Silicone Wound Contact Layer Dressing	5 x 7.5
	10 x 10
	15 x 15
	10 x 20

GMDN Code: 46855 (Wound Non-adherent Dressing, Permeable)

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).

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

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

Issued in Winsford, UK.

Kay McGrath
Regulatory Affairs Manager

07 January 2022
Date

Doc reference: Technical File F for Silicone Wound Contact Layer Dressing - TF-F, Revision 07, Issue Date: December 2021

Certificate No. MD78010

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

Advanced Medical Solutions Ltd TR-EC-001, rev 02

EC DECLARATION OF CONFORMITY

IN RELATION TO SILICONE WOUND CONTACT LAYER DRESSING

Advanced Medical Solutions Ltd, Premier Park, 33 Road One, Winsford Industrial Estate, Winsford, Cheshire, CW7 3RT, United Kingdom, declares that the Class IIb medical device manufactured by Advanced Medical Solutions and described below:

Product Name	Size (cm)
Silicone Wound Contact Layer Dressing	5 x 7.5
	10 x 10
	15 x 15
	20 x 20

GMDN Code: 43823 (Wound non-adherent dressing, Foam-style)

are in conformity with the essential requirements and provisions of Council Directive 93/42/EEC concerning medical devices (Medical Devices Directive) as amended by Directive 2007/47/EC, as transposed into UK Regulations by the Medical Devices (Amendment etc.) (EU Exit) Regulations 2019, SI 2019/1744, and applicable UK Statutory Instruments, and, where applicable, to and in conformity with the applicable harmonised standards of Annex II, Full Quality Assurance Certificate 4710-1698, under the supervision of our Notified Body, the British Standards Institution (0086).

Authorised Representative: Advanced Medical Solutions Ltd, Premier Park, 33 Road One, Winsford Industrial Estate, Winsford, Cheshire, CW7 3RT, UK

Standards Applied: Refer to the Notified Body's Certificate of Technical Conformity, 4710-1698

Issued in Winsford, UK

Kay McGivern
Regulatory Affairs Manager

Date: 21 November 2024

Our registered address is Apt Silicone Wound Contact Layer (Foam) - 15x15 Advanced Medical Solutions Ltd, Sandy Lane, Cheshire, SK9 7RT

Advanced Medical Solutions Ltd

EU Declaration of Conformity
Regulation (EU) 2017/745 on medical devices

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	Silicone Wound Contact Layer
Intended Purpose:	Silicone wound Contact Layer is intended for use on chronic and acute wounds with an appropriate secondary wound dressing. It is designed to lie between the wound bed and the secondary wound dressing to prevent the secondary wound dressing from sticking to the wound and allows exudate to pass into an absorbent secondary wound dressing.
Classification rule under Annex VIII:	Class IIb under Rule 4 (2nd 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
Silicone Wound Contact Layer	5 x 7.5 10 x 10 15 x 15 10 x 20	503274918105 01L8

Advanced Medical Solutions Ltd

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.

K McGrath

26 April 2023

Name Kay McGrath

Date

Position Regulatory Affairs Manager

Place of issuance Advanced Medical Solutions Ltd.

Doc reference: RTD-012 - SWCL Regulatory Technical Documentation, Rev 2, issue date April 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	Silicone Wound Contact Layer Dressing	5 x 7.5	10012016	**MDR DoC** EDC-012-001 Rev 1 CERTIFIED (signed) **MDD DoC** DoC_TF-F-001 Rev 07 CERTIFIED (signed)	APPROVED Certificate CE 01699	APPROVED Certificate MDR 729334
		10 x 10	10012017			
		15 x 15	10012014			
		10 x 20	10012015			
	BRAND NAME		**Catalogue Number [REF]**			
Medicline	NUR Sensitive Contact Layer	10 x 10	6003	**MDR DoC** EDC-012-004 Rev 1 DRAFT 1, DRAFT (unsigned)	N/A – Medicline will launch MDR product	Not yet CE marked DoC in draft
		15 x 15	6004			

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ActivHeal (AMS branded)	ActivHeal® Silicone Wound Contact Layer	5 x 7.5	9001241	**MDD DoC** DoC_TF-F-003 Rev 09 DRAFT (unsigned) **MDR DoC** EDC-012-002 Rev 1 DRAFT 1 DRAFT (unsigned)	CE marked	Not yet CE marked
		10 x 10	9001258			
		15 x 15	9001272			
		10 x 20	9001265			

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**
NUR Sensitive Contact Layer	6003	10 x 10	9001258	ActivHeal® Silicone Wound Contact Layer
	6004	15 x 15	9001272	

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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
Regulatory Affairs Associate
RegsRequests@admedsol.com
+44(0)1606 863500

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