

EC Declaration of Conformity

Silicone PHMB Foam Wound Dressings

This Declaration of Conformity is for the RESORBA Medical GmbH generic products, which are defined using their internal RESORBA Medical GmbH product names and/or codes as shown in Appendix A (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 RESORBA Medical GmbH branded and private label product variants.

According to Annex II of the Council Directive 93/42/EEC concerning medical devices we declare by sole responsibility that the medical device:

Name of product:	Silicone PHMB Foam Wound Dressings
Device classification according to Annex IX:	Class III
Article codes:	See attached Appendix A
Classification rule:	Rule 13
Intended use:	Silicone PHMB Foam Wound Dressings are primary wound dressings for use in the management of the moderate to heavily exuding chronic or acute wounds that effectively and rapidly absorbs wound exudate and creates the ideal environment for moist wound healing.
Manufactured by:	RESORBA Medical GmbH Am Flachmoor 16, 90475 Nuremberg, Germany

conforms with the essential requirements according Annex I and fulfills Annex II of the Council Directive 93/42/EEC concerning medical devices and all present valid legal regulatory requirements and harmonized standards.

The changes made comply with the transitional provisions of (EU) 2017/745 Article 120, such that the (EU) Declaration of Conformity (DD07 DoC dated 07 January 2021) has not been invalidated.

The design dossier was examined by:	Polish Centre for Testing and Certification 469 Puławska Street, 02-844 Warsaw, Poland
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Identification number:	1434
EC Certificate No:	1434-MDD-430/2020

This Declaration of Conformity is valid only for batches released successfully in line with RESORBA Medical GmbH's release criteria. RESORBA Medical GmbH declares that these devices manufactured by RESORBA Medical GmbH achieve conformity with the Council Directive 93/42/EEC via Annex II (Full Quality Product Assurance) at the time of release.

EC Declaration of Conformity

Silicone PHMB Foam Wound Dressings

Nuremberg,
RESORBA Medical GmbH

DocuSigned by Helen Topping
 | I approve this document
17-Jan-2024 | 13:11 GMT
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17-Jan-2024 | 13:11 GMT

Helen Topping, Regulatory & Clinical Director

Date

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Silicone PHMB Foam Wound Dressings

Appendix A – Article Codes

Description	Size (cm)
Silicone PHMB Adhesive Foam Dressing	8 x 8
	10 x 10
	10 x 15
	10 x 25
	10 x 30
	10 x 35
	12.5 x 12.5
	10 x 20
	15 x 15
	20 x 20
	19.5 x 18.5 (Sacral)
Silicone PHMB Adhesive Foam Dressing (Clear Film)	10 x 15
	10 x 20
	10 x 25
	10 x 30
	10 x 35
PHMB Non-adhesive Foam Dressing	5 x 5
	7.5 x 7.5
	10 x 10
	10 x 20
	15 x 15
	20 x 20



Advanced Medical Solutions Ltd

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The table below shows the Medicine product codes (soon to be CE marked to MDD) and their equivalent (MDD) CE marked AMS branded ActivHeal product codes (the only difference between the Medicine and ActivHeal product is the labelling (e.g. brand name, brand logo)).

Customer: MEDICLINE		Size (cm)	Customer: ActivHeal (AMS branded)	
BRAND NAME	Catalogue Number [REF]		Catalogue Number [REF]	BRAND NAME
nürofoam® Surgical PHMB Silicone Foam Border Dressing	4006	10 x 20	9027463	ActivHeal® PHMB Foam Silicone Border
	4007	10 x 25	9027470	
	4010	10 x 30	ActivHeal don't take this size	
nürofoam® PHMB Silicone Sacral Foam Dressing	4011	18.5 x 19.5 Sacral	9027500	
	4005	10 x 10	9027456	
	4008	15 x 15	9027487	
nürofoam® Sensitive Border PHMB Foam Dressing	4009	20 x 20	9027494	ActivHeal® Non-adhesive PHMB Foam
	7008	10 x 10	9027531	
	7009	15 x 15	9027555	
nürofoam® PHMB Non-adhesive Foam Dressing	7010	10 x 20	9027548	
	7011	20 x 20	9027562	



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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 PHMB Adhesive Foam Dressing	8 x 8	10013763	MDD DoC DD07-001 Rev 5 CERTIFIED (signed)	APPROVED DE Cert 1434-MDD- 430.2020	Not yet approved
		10 x 10	10013764			
		10 x 15	10014423			
		10 x 25	10014424			
		10 x 30	10013770			
		10 x 35	10014425			
		12.5 x 12.5	10013765			
		10 x 20	10013433			
		15 x 15	10013767			
		20 x 20	10013768			
	Silicone PHMB Adhesive Foam Dressing (Clear Film)	18.5 x 19.5 Sacral	10013769			
		10 x 15	10014737			
		10 x 20	10014738			
		10 x 25	10014739			
		10 x 30	10014740			





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Medicine	PHMB Non-adhesive Foam Dressing	10 x 35	10014741	MDD DoC DD07-006 Rev 1, DRAFT 1 (unsigned)	Not yet CE marked DoC in draft	N/A – product not yet approved
		5 x 5	10013771			
		7.5 x 7.5	10013772			
		10 x 10	10013773			
		10 x 20	10013774			
		15 x 15	10013775			
		20 x 20	10013776			
		BRAND NAME				
	nürofoam® Surgical PHMB Silicone Foam Border Dressing	10 x 20	4006			
		10 x 25	4007			
		10 x 30	4010			
	nürofoam® PHMB Silicone Sacral Foam Dressing	18.5 x 19.5 Sacral	4011			
	nürofoam® Sensitive Border PHMB Foam Dressing	10 x 10	4005			
		15 x 15	4008			
		20 x 20	4009			



UK Authorised Economic Operator



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	nürofoam® PHMB Non-adhesive Foam Dressing	10 x 10	7008			
		15 x 15	7009			
		10 x 20	7010			
		20 x 20	7011			
ActivHeal	ActivHeal® PHMB Foam Silicone Border	8 x 8	9027449	MDD DoC DD07-002 Rev 4, CERTIFIED (signed)	CE marked	N/A – product not yet approved
		10 x 10	9027456			
		12.5 x 12.5	9027463			
		10 x 20	9027470			
		15 x 15	9027487			
		20 x 20	9027494			
		18.5 x 19.5 Sacral	9027500			
		5 x 5	9027517			
ActivHeal	ActivHeal® Non-adhesive PHMB Foam	7.5 x 7.5	9027524		CE marked	N/A – product not yet approved
		10 x 10	9027531			
		10 x 20	9027548			
		15 x 15	9027555			
		20 x 20	9027562			





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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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