



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

Size cm [inches]	14-2A	14-2AP	1-2C & 1-2CP	1-21A	1-2B	1-21DP Aquafiber	1-21DP Reinforced Aquafiber	HPD 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 42						✓	✓	
2 x 46								✓
2.5 x 42							✓	
2.5 x 30.5	✓	✓	✓		✓			✓
2.5 x 30		✓		✓				
2.5 x 32	✓	✓	✓					
2.5 x 37	✓							
3 x 44	✓	✓						
2.7 x 34	✓							
Fluffy Ropes								
30cm	✓			✓	✓			
34cm	✓							
37cm	✓							

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





Advanced Medical Solutions Ltd

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Registered in England 2666957

TF-A-001, Rev. 10

(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).

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

GMDN Code: 43186 - Exudate-absorbent dressing, hydrophilic-gel - A sterile wound covering, typically made of a hydrocolloid, hydrofibre, or alginate (salts and acids extracted from seaweed), intended to produce a water-absorbent gel upon contact with wound exudate; it does not contain an antimicrobial agent. The device assists in wound healing by absorbing exudate in wounds (e.g., ulcers, burns, surgical wounds, lacerations, abrasions) for minimal wound maceration, allowing wound debridement, and creating a moist wound-healing environment. The device may be in the form of a flat sheet/film, ribbon, rope, foam, liquid, paste, or powder. After application, this device cannot be reused. Products - Alginates (including re-enforced), Hydrocolloids.

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.

Adam Gregory
Regulatory Affairs Manager

26 NOVEMBER 2020

Date

Doc reference: Technical File A - Non-woven Dressings Product Family – TF-A Revision 08, Issue Date October 2019





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26 November 2020

To whom it may concern,

Product Confirmation Statement

Tegaderm Alginate HI Dressing

Product Codes 90110, 90112, 90114, 90120

Further to your enquiry I am able to confirm that the product Tegaderm Alginate HI is identical to the Advanced Medical Solutions Limited product 1-2B Alginate dressing. Whilst the branding differs, the formulation, raw materials, methods of manufacturing and testing as well as the packaging are identical.

Signed on behalf of Advanced Medical Solutions Limited

Adam Gregory
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Certificate No. MD 78010