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

Advanced Medical Solutions Ltd

TF-A 005, Rev 12

Addendum to: TF-A-005, Rev. 6, dated 20 May 2020

EC DECLARATION OF CONFORMITY IN RELATION TO BIATAIN® ALGINATE TECHNICAL FILE A

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:

Size	AMS Product Code	Coloplast Product Name	Coloplast Product Code
5x5cm	10014034	Biatain® Alginate	3705
10x10cm	10014035		3710
15x15cm	10014036		3715
3x44cm	10014037		3740
3x44cm	10014038		3743

- 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.

The changes made comply with the transitional provisions of (EU) 2017/745 Article 120, such that the (EU) Declaration of Conformity (TF-A-005 dated 20 May 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.

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DocuSigned by Kay McGrath
Kay McGrath | I approve this document
27 Nov 2023 | 10:57 GMT
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27-Nov-2023 | 11:39 GMT

Kay McGrath

Date

Regulatory Affairs Manager

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