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By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 01699**

Issued To: **Advanced Medical Solutions Ltd**
Premier Park
33 Road One
Winsford Industrial Estate
Winsford
Cheshire
CW7 3RT
United Kingdom

In respect of:

The design, development and manufacture of sterile medicated and non-medicated alginate/CMC blended wound dressings, alginate wound dressings, polyurethane foam wound dressings, hydrocolloid wound dressings, amorphous hydrogel and silicone wound contact layer.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack

Gary E Slack, Senior Vice President - Medical Devices

First Issued: **1997-09-03** Date: **2021-04-06** Expiry Date: **2024-05-26**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
A member of BSI Group of Companies.

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Supplementary Information to CE 01699

Issued To:

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Number	Device Name	Intended Purpose per IFU
Class III		
---	Silver Alginate I Antimicrobial Wound Dressing	See CE 70851
---	Silver Alginate IV Antimicrobial Wound Dressing	See CE 608297
---	Silver Alginate II Antimicrobial Wound Dressing	See CE 97750
---	PHMB Antimicrobial Foam Wound Dressing	See CE 600773
Class IIb		
43186	Non-woven dressings	Moderate to heavily exuding chronic and acute wounds. Single use.
44970	Foam Dressings	Moderate to heavily exuding chronic and acute wounds. Single use.
44970	Lite Foam Dressings	Non to lightly exuding chronic and acute wounds. Single use.
47764	Hydrogels	Necrotic and sloughy wounds with low exudates. Single use.
46855	Silicone Wound Contact Layer	Nil to heavily exuding chronic and acute wounds (with an appropriate secondary dressing). Single use.
43186	Hydrocolloid dressings	Light to moderately exuding chronic and acute wounds. Single use.

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