EC Design-Examination Certificate

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

No. **CE 70851**

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

In respect of:

Hydro-Alginate Antimicrobial Wound Dressing with Silver

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding 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, Senior Vice President Medical Devices

First Issued: **2005-01-28** Date: **2021-03-23** Expiry Date: **2024-05-26**

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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, Senior Vice President Medical Devices

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

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EC Certificate - Full Quality Assurance System

Supplementary Information to CE 01699

Issued To:

Advanced Medical Solutions Ltd
Premier Park
33 Road One
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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.

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

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Advanced Medical Solutions Ltd

Premier Park, 33 Road One,
Winsford Industrial Estate,
Cheshire, CW7 3RT,
United Kingdom

3rd January 2024

Notified Body Confirmation Letter

Reference: EU2023-607/755601

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, **BSI Group The Netherlands B.V.**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **2797** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Advanced Medical Solutions Ltd

Premier Park, 33 Road One,
Winsford Industrial Estate,
Cheshire, CW7 3RT,
United Kingdom

SRN Number: GB-MF-000008822

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of BSI Group The Netherlands B.V.,

Graeme Tunbridge
Senior Vice President, Medical Devices

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Foam Lite Basic UDI-DI: 50327491810201KR	Class IIb excluding Class IIb implantable non-WET	N/A	MDD certificate# CE 01699 Expiry date: 26-May-2024 BSI NL NB# 2797
Silicone tri-laminate Foam; Tri-laminate Foam (non-adhesive); Bi-laminate Foam (adhesive); Bi-laminate Foam (non-adhesive, heel) Basic UDI-DI: 50327491810202KT	Class IIb excluding Class IIb implantable non-WET	N/A	MDD certificate# CE 01699 Expiry date: 26-May-2024 BSI NL NB# 2797
Silicone Wound Contact Layer Basic UDI-DI: 50327491810501L8	Class IIb excluding Class IIb implantable non-WET	N/A	MDD certificate# CE 01699 Expiry date: 26-May-2024 BSI NL NB# 2797
1-21A alginate; 1-2B alginate; 1-21DP reinforced alginate Basic UDI-DI: 50327491810103KQ	Class IIb excluding Class IIb implantable non-WET	N/A	MDD certificate# CE 01699 Expiry date: 26-May-2024 BSI NL NB# 2797
41-2AP CMC/alginate; 14-2A CMC/alginate; 14-2AP CMC/alginate Basic UDI-DI: 50327491810101KL	Class IIb excluding Class IIb implantable non-WET	N/A	MDD certificate# CE 01699 Expiry date: 26-May-2024 BSI NL NB# 2797
Silver alginate I (Hydro-alginate antimicrobial wound dressing with Silver) Basic UDI-DI: 50327491810901LU	Class III	N/A	MDD certificate# CE 01699 Expiry date: 26-May-2024 MDD certificate# CE 70851 Expiry date: 26-May-2024 BSI NL NB# 2797
Silver alginate II (Silver alginate II antimicrobial wound dressing with silver sodium hydrogen zirconium phosphate) Basic UDI-DI: 50327491810902LW	Class III	N/A	MDD certificate# CE 01699 Expiry date: 26-May-2024 MDD certificate# CE 97750 Expiry date: 26-May-2024 BSI NL NB# 2797
Silver alginate IV (Silver alginate IV antimicrobial wound dressing with silver carbonate) Basic UDI-DI: 50327491810903LY	Class III	N/A	MDD certificate# CE 01699 Expiry date: 26-May-2024 MDD certificate# CE 608297 Expiry date: 26-May-2024 BSI NL NB# 2797

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Silicone PHMB Foam wound dressings Basic UDI-DI: 50327491811002KQ	Class III	N/A	MDD certificate# 1434-MDD-431/2020 Expiry date: 27-May-2024 MDD certificate# 1434-MDD-430/2020 Expiry date: 27-May-2024 NB# 1434

Confirmation Letter Revision History

Date	Action
2024/01/03	Initial issue