Advanced Medical Solutions Ltd

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Premier Park, 33 Road One
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Registered in England 2666957 VAT No. GB 636 5551 27

Medicline D.O.O
Vinogradska 217
Osijek 31000
Croatia.

Date: 6th June 2025

CERTIFICATE OF CONFORMANCE

This is to certify that the product listed below has been manufactured and sterilised according to Advanced Medical Solutions specifications and procedures in compliance with Good Manufacturing Practice for Medical Devices. This product has been validated per ISO guidelines to provide a Sterilty Assurance Level of 10^{-6}.

All internal inspection and test requirements have been met. Test results are on file and available upon request.

Part Number	Description	Manufacturing Lot Number	Sterile Lot Number	Quantity (cartons)
10016981	Medicline Nurocel Extra Fibrous Cellulose Dressing HPD 10x10cm Ref: 2010	W00075897	2163-11995A	500 ctns

Customer Order Number: June 25

Prepared By:

Name: Christine Jones
Quality Assurance

Verified By:

Name: Ian Platt
Quality Assurance

Certificate No. MD78010

Lot 75897 23 MAY 2025

STERIS: Gamma Certificate Of Processing

Prepared For ADVANCED MEDICAL SOLUTIONS LTD (8544)

Gamma Process Run ID 2163-11995A

Product Code	Lot Number	Quantity	UOM
PROCESSING FAMILY 1	Multiple	10	Pallet

Validation Reference Number: 1.0037

Processing Run Start Date 19-May-2025 2:22 AM

Processing Run End Date 19-May-2025 7:02 AM

Specified Dose Range (kGy)	**25.0 - 40.0**	**Calculated Min Dose (kGy)**	**26.9**
Reference Dose Range (kGy)	**31.7 - 36.6**	**Calculated Max Dose (kGy)**	**38.6**

PO Number 2051706

Product meets Customer specifications; zero nonconformities occurred during this irradiation run.

Other Information

QTY 571 CASES + 4 SAMPLES, 75897/01, 75898/06/07/08, 75903/02/03,75906/03/04, 75950/01/02

Gamma Process Run Approval authorized by STERIS

DateTime Esigned 21-May-2025 5:51 PM

Operating facilities is in compliance with applicable state and federal regulations (FDA, NRC, EPA, and OSHA) and provide services under a quality system which meets the requirements of FDA QSR, EN/ISO 13485, and in alignment with EN ANSI/AAMI/ISO 11137. STERIS certifies that these processed items received the indicated doses within the precision and accuracy of the dosimetry system used. Legal Entity: Synergy Health Sterilisation UK, a STERIS Company.

Processing Location

Roydsdale Way
Euroway Trading Estate
Bradford, West Yorkshire
BD4 6SE
Phone: +44 (0) 1274-686011

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Date: 9th June 2025

CERTIFICATE OF CONFORMANCE

This is to certify that the product listed below has been manufactured and sterilised according to Advanced Medical Solutions specifications and procedures in compliance with Good Manufacturing Practice for Medical Devices. This product has been validated per ISO guidelines to provide a Sterilty Assurance Level of 10^{-6}.

All internal inspection and test requirements have been met. Test results are on file and available upon request.

Part Number	Description	Manufacturing Lot Number	Sterile Lot Number	Quantity (cartons)
10016992	Medicline Nurofoam Non- Adhesive Foam Dressing 10x20cm Ref: 5013	W00076122	2163-12210A	500 ctns

Customer Order Number: June 25

Prepared By:

Name: Christine Jones
Quality Assurance

Verified By:

Name: Ian Platt
Quality Assurance

LOT 76122 06 JUN 2025

STERIS: Gamma Certificate Of Processing

Prepared For ADVANCED MEDICAL SOLUTIONS LTD (8544)

Gamma Process Run ID 2163-12210A

Product Code	Lot Number	Quantity	UOM
PROCESSING FAMILY 1	Multiple	20	Pallet

Validation Reference Number: 1.0037

Processing Run Start Date 30-May-2025 10:26 PM

Processing Run End Date 31-May-2025 5:29 AM

Specified Dose Range (kGy)	**25.0 - 40.0**	**Calculated Min Dose (kGy)**	**25.9**
Reference Dose Range (kGy)	**31.7 - 36.6**	**Calculated Max Dose (kGy)**	**38.5**

PO Number 2051706

Product meets Customer specifications; zero nonconformities occurred during this irradiation run.

Other Information

QTY 1805 CASES + 5 SAMPLES, 76030/03/04/05, 76035/01, 76089/01/02/03/04/05, 76092/01/02, 76093/07/08/09, 76096/01/02/03/04, 76122/01/02

Gamma Process Run Approval authorized by STERIS

DateTime Esigned 03-Jun-2025 1:12 PM

Operating facilities is in compliance with applicable state and federal regulations (FDA, NRC, EPA, and OSHA) and provide services under a quality system which meets the requirements of FDA QSR, EN/ISO 13485, and in alignment with EN ANSI/AAMI/ISO 11137. STERIS certifies that these processed items received the indicated doses within the precision and accuracy of the dosimetry system used. Legal Entity: Synergy Health Sterilisation UK, a STERIS Company.

Processing Location

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Croatia.

Date: 10th June 2025

CERTIFICATE OF CONFORMANCE

This is to certify that the product listed below has been manufactured and sterilised according to Advanced Medical Solutions specifications and procedures in compliance with Good Manufacturing Practice for Medical Devices. This product has been validated per ISO guidelines to provide a Sterilty Assurance Level of 10^{-6}.

All internal inspection and test requirements have been met. Test results are on file and available upon request.

Part Number	Description	Manufacturing Lot Number	Sterile Lot Number	Quantity (cartons)
10016996	Medicline Nurofoam Sensitive Silicone Border Foam Dressing 15x15cm Ref: 6011	W00076127	ISAC-8-020625-7	700 ctns

Customer Order Number: June 25

Prepared By:

Name: Christine Jones
Quality Assurance

Verified By:

Name: Ian Platt
Quality Assurance

Certificate No. MD78010

LOT 76127 10 JUN 2025

ANDERSEN CALEDONIA

CERTIFICATE OF CONFORMANCE

FOR ETHYLENE OXIDE PROCESSING

GENERAL	
Andersen Caledonia Ethylene Oxide Pattern	20102
Customer	AMS Winsford
Andersen Caledonia Batch Number	ISAC-8-020625-7
Customer Reference Numbers	PO 2051335 SP020625-6 x 4 Pallets Part No:10016996 Lot: W00076127 x 42 (01) Part No:10015838 Lot: W00075944 x 19 (01) Part No:10016996 Lot: W00076127 x 29 (02) Part No:10015841 Lot: W00076126 x 70 (01)
Sterilisation Process Completion Date	05th June 2025
Additional Information	Load Temperature Specification: ≥ 7°C on arrival. Actual: 17.4°C

N.B Sterilisation process complete = heated aeration is complete
See checklist for all process parameters

AERATION PROCESS

PARAMETER	SPECIFICATION	ACTUAL
Heated Aeration temperature	36 - 46°C	Minimum – Maximum 39.1 – 41.8
Heated Aeration dwell time	08 to 72 hours	08.02

Customer ambient aeration requirement	N/A
Date and time ambient aeration complete	N/A
Where applicable - Goods should not be opened and are not fit for use until the stated ambient aeration date and time is completed.	

BIOLOGICAL INDICATOR TESTING

Biological indicator species used	*Bacillus atrophaeus*
Number of Biological Indicators used	20
Biological Indicator batch number	G251
Number of endospores per Biological Indicator	Minimum 1.0×10^6
Positive and negative controls satisfactory	Yes
Biological indicator cultures clear after 2 Days (procedure 4047)	Yes
Biological Indicator process dates	05/06/25 to 07/06/25

Biological indicators meet the requirements of ISO 11138 and minimum requirements of ISO 11135

The product referenced, as described by the Customer, was processed at Andersen Caledonia using Ethylene Oxide.
The process met the specification for validated cycle 20102

Approved by: [signature] Date: 09 JUN 2025

Andersen Caledonia Limited, Caledonian House, Phoenix Crescent, Strathclyde Business Park, Lanarkshire, ML4 3NJ, Scotland, United Kingdom.
Tel: + 44 01698 844476 E-mail: sterilisation@andersencaledonia.com www.andersencaledonia.com

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Medicline D.O.O
Vinogradska 217
Osijek 31000
Croatia.

Date: 10th June 2025

CERTIFICATE OF CONFORMANCE

This is to certify that the product listed below has been manufactured and sterilised according to Advanced Medical Solutions specifications and procedures in compliance with Good Manufacturing Practice for Medical Devices. This product has been validated per ISO guidelines to provide a Sterilty Assurance Level of 10^{-6}.

All internal inspection and test requirements have been met. Test results are on file and available upon request.

Part Number	Description	Manufacturing Lot Number	Sterile Lot Number	Quantity (cartons)
10016987	Medicline Nurofoam PHMB Silicone Sacral Foam Dressing 18.5x19.5cm Ref: 4011	W00076128	ISAC-9-020625-5	670 ctns

Customer Order Number: June 25

Prepared By:

Name: Christine Jones
Quality Assurance

Verified By:

Name: Ian Platt
Quality Assurance

Lot 76128 09 JUN 2025

ANDERSEN CALEDONIA

CERTIFICATE OF CONFORMANCE

FOR ETHYLENE OXIDE PROCESSING

GENERAL	
Andersen Caledonia Ethylene Oxide Pattern	10102
Customer	AMS Winsford
Andersen Caledonia Batch Number	ISAC-9-020625-5
Customer Reference Numbers	PO 2051335 SP020625-6 x 9 Pallets Part No:10016990 Lot: W00076121 x 25 (01) Part No:10016990 Lot: W00076121 x 21 (02) Part No:10016987 Lot: W00076128 x 8 (03) Part No:10015840 Lot: W00075996 x 21 (01)
Sterilisation Process Completion Date	03rd June 2025
Additional Information	Load Temperature Specification: ≥ 7°C on arrival. Actual: 18.1°C

N.B Sterilisation process complete = heated aeration is complete
See checklist for all process parameters

AERATION PROCESS

PARAMETER	SPECIFICATION	ACTUAL
Heated Aeration temperature	36 - 46°C	Minimum – Maximum 39.2 – 41.6
Heated Aeration dwell time	08 to 72 hours	08.08

Customer ambient aeration requirement	N/A
Date and time ambient aeration complete	N/A
Where applicable - Goods should not be opened and are not fit for use until the stated ambient aeration date and time is completed.	

BIOLOGICAL INDICATOR TESTING

Biological indicator species used	*Bacillus atrophaeus*
Number of Biological Indicators used	22
Biological Indicator batch number	G251
Number of endospores per Biological Indicator	Minimum 1.0×10^6
Positive and negative controls satisfactory	Yes
Biological indicator cultures clear after 2 Days (procedure 4047)	Yes
Biological Indicator process dates	03/06/25 to 06/06/25

Biological indicators meet the requirements of ISO 11138 and minimum requirements of ISO 11135

The product referenced, as described by the Customer, was processed at Andersen Caledonia using Ethylene Oxide. The process met the specification for validated cycle 10102

Approved by: [signature] Date: 06 JUN 2025

Andersen Caledonia Limited, Caledonian House, Phoenix Crescent, Strathclyde Business Park, Lanarkshire, ML4 3NJ, Scotland, United Kingdom.
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ANDERSEN CALEDONIA

CERTIFICATE OF CONFORMANCE

FOR ETHYLENE OXIDE PROCESSING

GENERAL	
Andersen Caledonia Ethylene Oxide Pattern	10102
Customer	AMS Winsford
Andersen Caledonia Batch Number	ISAC-9-020625-5
Customer Reference Numbers	PO 2051335 SP020625-6 x 9 Pallets Part No:10016475 Lot: W00076125 x 38 (02) Part No:10016987 Lot: W00076128 x 30 (02) Part No:10015841 Lot: W00076126 x 11 (02) Part No:10016989 Lot: W00076124 x 51 (01) Part No:10016987 Lot: W00076128 x 30 (01)
Sterilisation Process Completion Date	03rd June 2025
Additional Information	Load Temperature Specification: ≥ 7°C on arrival. Actual: 18.1°C

N.B Sterilisation process complete = heated aeration is complete
See checklist for all process parameters

AERATION PROCESS

PARAMETER	SPECIFICATION	ACTUAL
Heated Aeration temperature	36 - 46°C	Minimum – Maximum 39.2 – 41.6
Heated Aeration dwell time	08 to 72 hours	08.08

Customer ambient aeration requirement	N/A
Date and time ambient aeration complete	N/A
Where applicable - Goods should not be opened and are not fit for use until the stated ambient aeration date and time is completed.	

BIOLOGICAL INDICATOR TESTING

Biological indicator species used	*Bacillus atrophaeus*
Number of Biological Indicators used	22
Biological Indicator batch number	G251
Number of endospores per Biological Indicator	Minimum 1.0×10^6
Positive and negative controls satisfactory	Yes
Biological indicator cultures clear after 2 Days (procedure 4047)	Yes
Biological Indicator process dates	03/06/25 to 06/06/25

Biological indicators meet the requirements of ISO 11138 and minimum requirements of ISO 11135

The product referenced, as described by the Customer, was processed at Andersen Caledonia using Ethylene Oxide. The process met the specification for validated cycle 10102

Approved by: Date: 06 JUN 2025

Andersen Caledonia Limited, Caledonian House, Phoenix Crescent, Strathclyde Business Park, Lanarkshire, ML4 3NJ, Scotland, United Kingdom.
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Vinogradska 217
Osijek 31000
Croatia.

Date: 10th June 25

CERTIFICATE OF CONFORMANCE

This is to certify that the product listed below has been manufactured and sterilised according to Advanced Medical Solutions specifications and procedures in compliance with Good Manufacturing Practice for Medical Devices. This product has been validated per ISO guidelines to provide a Sterilty Assurance Level of 10^{-6}.

All internal inspection and test requirements have been met. Test results are on file and available upon request.

Part Number	Description	Manufacturing Lot Number	Sterile Lot Number	Quantity (cartons)
10016984	Medicline Alginur Ag Silver Alginate Antimicrobial Wound Dressing 10x10cm Ref: 3010	W00076103	2163-12285A	600 ctns

Customer Order Number: June 25

Prepared By:

Name: Christine Jones
Quality Assurance

Verified By:

Name: Ian Platt
Quality Assurance

Certificate No. MD78010

LOT 76103 10 JUN 2025

STERIS: Gamma Certificate Of Processing

Prepared For ADVANCED MEDICAL SOLUTIONS LTD (8544)

Gamma Process Run ID 2163-12285A

Product Code	Lot Number	Quantity	UOM
PROCESSING FAMILY 1	MULTIPLE	16	Pallet

Validation Reference Number: 1.0037

Processing Run Start Date 06-Jun-2025 1:46 AM

Processing Run End Date 06-Jun-2025 7:27 AM

Specified Dose Range (kGy)	**25.0 - 40.0**	**Calculated Min Dose (kGy)**	**26.3**
Reference Dose Range (kGy)	**31.7 - 36.6**	**Calculated Max Dose (kGy)**	**39.1**

PO Number 2051706

Product meets Customer specifications; zero nonconformities occurred during this irradiation run.

Other Information

QTY 1419 CASES + 5 SAMPLES, 75979/01/02/03, 76035/03/04, 76089/10/11/12/13/14, 76090/01, 76102/01, 76103/01, 76235/01, 76234/01, 76244/01

Gamma Process Run Approval authorized by STERIS

DateTime Esigned 06-Jun-2025 11:45 AM

Operating facilities is in compliance with applicable state and federal regulations (FDA, NRC, EPA, and OSHA) and provide services under a quality system which meets the requirements of FDA QSR, EN/ISO 13485, and in alignment with EN ANSI/AAMI/ISO 11137. STERIS certifies that these processed items received the indicated doses within the precision and accuracy of the dosimetry system used. Legal Entity: Synergy Health Sterilisation UK, a STERIS Company.

Processing Location

Roydsdale Way
Euroway Trading Estate
Bradford, West Yorkshire
BD4 6SE
Phone: +44 (0) 1274-686011

Document ID: 47873

Advanced Medical Solutions Ltd

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Vinogradska 217
Osijek 31000
Croatia.

Date: 10th June 2025

CERTIFICATE OF CONFORMANCE

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All internal inspection and test requirements have been met. Test results are on file and available upon request.

Part Number	Description	Manufacturing Lot Number	Sterile Lot Number	Quantity (cartons)
10016989	Medicline Nurofoam Adhesive Foam Dressing 10x10cm Ref: 5010	W00076124	ISAC-9-020625-5	500 ctns

Customer Order Number: June 25

Prepared By:

Name: Christine Jones
Quality Assurance

Verified By:

Name: Ian Platt
Quality Assurance

Certificate No. MD78010

LOT 76124 09 JUN 2025

ANDERSEN CALEDONIA

CERTIFICATE OF CONFORMANCE

FOR ETHYLENE OXIDE PROCESSING

GENERAL	
Andersen Caledonia Ethylene Oxide Pattern	10102
Customer	AMS Winsford
Andersen Caledonia Batch Number	ISAC-9-020625-5
Customer Reference Numbers	PO 2051335 SP020625-6 x 9 Pallets Part No:10016990 Lot: W00076121 x 25 (01) Part No:10016990 Lot: W00076121 x 21 (02) Part No:10016987 Lot: W00076128 x 8 (03) Part No:10015840 Lot: W00075996 x 21 (01)
Sterilisation Process Completion Date	03rd June 2025
Additional Information	Load Temperature Specification: ≥ 7°C on arrival. Actual: 18.1°C

N.B Sterilisation process complete = heated aeration is complete
See checklist for all process parameters

AERATION PROCESS

PARAMETER	SPECIFICATION	ACTUAL
Heated Aeration temperature	36 - 46°C	Minimum – Maximum 39.2 – 41.6
Heated Aeration dwell time	08 to 72 hours	08.08

Customer ambient aeration requirement	N/A
Date and time ambient aeration complete	N/A
Where applicable - Goods should not be opened and are not fit for use until the stated ambient aeration date and time is completed.	

BIOLOGICAL INDICATOR TESTING

Biological indicator species used	*Bacillus atrophaeus*
Number of Biological Indicators used	22
Biological Indicator batch number	G251
Number of endospores per Biological Indicator	Minimum 1.0×10^6
Positive and negative controls satisfactory	Yes
Biological indicator cultures clear after 2 Days (procedure 4047)	Yes
Biological Indicator process dates	03/06/25 to 06/06/25

Biological indicators meet the requirements of ISO 11138 and minimum requirements of ISO 11135

The product referenced, as described by the Customer, was processed at Andersen Caledonia using Ethylene Oxide.
The process met the specification for validated cycle 10102

Approved by: [signature] Date: 06 JUN 2025

Andersen Caledonia Limited, Caledonian House, Phoenix Crescent, Strathclyde Business Park, Lanarkshire, ML4 3NJ, Scotland, United Kingdom.
Tel: + 44 01698 844476 E-mail: sterilisation@andersencaledonia.com www.andersencaledonia.com

CERTIFICATE OF CONFORMANCE

FOR ETHYLENE OXIDE PROCESSING

GENERAL	
Andersen Caledonia Ethylene Oxide Pattern	10102
Customer	AMS Winsford
Andersen Caledonia Batch Number	ISAC-9-020625-5
Customer Reference Numbers	PO 2051335 SP020625-6 x 9 Pallets Part No:10016475 Lot: W00076125 x 38 (02) Part No:10016987 Lot: W00076128 x 30 (02) Part No:10015841 Lot: W00076126 x 11 (02) Part No:10016989 Lot: W00076124 x 51 (01) Part No:10016987 Lot: W00076128 x 30 (01)
Sterilisation Process Completion Date	03rd June 2025
Additional Information	Load Temperature Specification: ≥ 7°C on arrival. Actual: 18.1°C

N.B Sterilisation process complete = heated aeration is complete
See checklist for all process parameters

AERATION PROCESS

PARAMETER	SPECIFICATION	ACTUAL
Heated Aeration temperature	36 - 46°C	Minimum – Maximum 39.2 – 41.6
Heated Aeration dwell time	08 to 72 hours	08.08

Customer ambient aeration requirement	N/A
Date and time ambient aeration complete	N/A
Where applicable - Goods should not be opened and are not fit for use until the stated ambient aeration date and time is completed.	

BIOLOGICAL INDICATOR TESTING

Biological indicator species used	*Bacillus atrophaeus*
Number of Biological Indicators used	22
Biological Indicator batch number	G251
Number of endospores per Biological Indicator	Minimum 1.0×10^6
Positive and negative controls satisfactory	Yes
Biological indicator cultures clear after 2 Days (procedure 4047)	Yes
Biological Indicator process dates	03/06/25 to 06/06/25

Biological indicators meet the requirements of ISO 11138 and minimum requirements of ISO 11135

The product referenced, as described by the Customer, was processed at Andersen Caledonia using Ethylene Oxide. The process met the specification for validated cycle 10102

Approved by: Date: 06 JUN 2025

Andersen Caledonia Limited, Caledonian House, Phoenix Crescent, Strathclyde Business Park, Lanarkshire, ML4 3NJ, Scotland, United Kingdom.
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Osijek 31000
Croatia.

Date: 10th June 2025

CERTIFICATE OF CONFORMANCE

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All internal inspection and test requirements have been met. Test results are on file and available upon request.

Part Number	Description	Manufacturing Lot Number	Sterile Lot Number	Quantity (cartons)
10016990	Medicline Nurofoam Adhesive Foam Dressing 15x15cm Ref: 5011	W00076121	ISAC-9-020625-5	450 ctns

Customer Order Number: June 25

Prepared By:

Name: Christine Jones
Quality Assurance

Verified By:

Name: Ian Platt
Quality Assurance

LOT 76121 09 JUN 2025

ANDERSEN CALEDONIA

CERTIFICATE OF CONFORMANCE

FOR ETHYLENE OXIDE PROCESSING

GENERAL	
Andersen Caledonia Ethylene Oxide Pattern	10102
Customer	AMS Winsford
Andersen Caledonia Batch Number	ISAC-9-020625-5
Customer Reference Numbers	PO 2051335 SP020625-6 x 9 Pallets Part No:10016990 Lot: W00076121 x 25 (01) Part No:10016990 Lot: W00076121 x 21 (02) Part No:10016987 Lot: W00076128 x 8 (03) Part No:10015840 Lot: W00075996 x 21 (01)
Sterilisation Process Completion Date	03rd June 2025
Additional Information	Load Temperature Specification: ≥ 7°C on arrival. Actual: 18.1°C

N.B Sterilisation process complete = heated aeration is complete
See checklist for all process parameters

AERATION PROCESS

PARAMETER	SPECIFICATION	ACTUAL
Heated Aeration temperature	36 - 46°C	Minimum – Maximum 39.2 – 41.6
Heated Aeration dwell time	08 to 72 hours	08.08

Customer ambient aeration requirement	N/A
Date and time ambient aeration complete	N/A
Where applicable - Goods should not be opened and are not fit for use until the stated ambient aeration date and time is completed.	

BIOLOGICAL INDICATOR TESTING

Biological indicator species used	*Bacillus atrophaeus*
Number of Biological Indicators used	22
Biological Indicator batch number	G251
Number of endospores per Biological Indicator	Minimum 1.0×10^6
Positive and negative controls satisfactory	Yes
Biological indicator cultures clear after 2 Days (procedure 4047)	Yes
Biological Indicator process dates	03/06/25 to 06/06/25

Biological indicators meet the requirements of ISO 11138 and minimum requirements of ISO 11135

The product referenced, as described by the Customer, was processed at Andersen Caledonia using Ethylene Oxide.
The process met the specification for validated cycle 10102

Approved by: Date: 06 JUN 2025

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Registered in England 2666957 VAT No. GB 636 5551 27

Advanced Medical Solutions Ltd

Medicline D.O.O
Vinogradska 217
Osijek 31000
Croatia.

Date: 13th June 2025

CERTIFICATE OF CONFORMANCE

This is to certify that the product listed below has been manufactured and sterilised according to Advanced Medical Solutions specifications and procedures in compliance with Good Manufacturing Practice for Medical Devices. This product has been validated per ISO guidelines to provide a Sterilty Assurance Level of 10^{-6}.

All internal inspection and test requirements have been met. Test results are on file and available upon request.

Part Number	Description	Manufacturing Lot Number	Sterile Lot Number	Quantity (cartons)
10016993	Medicline Nurofoam Non- Adhesive Foam Dressing 20x20cm Ref: 5014	W00076225	2163-12419A	600 ctns

Customer Order Number: June 25

Prepared By:

Name: Christine Jones
Quality Assurance

Verified By:

Name: Ian Platt
Quality Assurance

Certificate No. MD78010

LOT 76225 13 JUN 2025

STERIS: Gamma Certificate Of Processing

Prepared For ADVANCED MEDICAL SOLUTIONS LTD (8544)

Gamma Process Run ID 2163-12419A

Product Code	Lot Number	Quantity	UOM
PROCESSING FAMILY 1	MULTIPLE	23	Pallet

Validation Reference Number: 1.0037

Processing Run Start Date 11-Jun-2025 12:28 PM

Processing Run End Date 11-Jun-2025 9:48 PM

Specified Dose Range (kGy)	**25.0 - 40.0**	**Calculated Min Dose (kGy)**	**26.8**
Reference Dose Range (kGy)	**31.7 - 36.6**	**Calculated Max Dose (kGy)**	**38.4**

PO Number 2051706

Product meets Customer specifications; zero nonconformities occurred during this irradiation run.

Other Information

QTY 1947 CASES + 5 SAMPLES, 75981/05/06/07/08/09/10, 76035/05/06/07/08/09/10/11, 76202/01, 76205/12, 76225/01/02, 76324/01, 76323/01/02/03/04,76363/01

Gamma Process Run Approval authorized by STERIS

DateTime Esigned 12-Jun-2025 11:08 AM

Operating facilities is in compliance with applicable state and federal regulations (FDA, NRC, EPA, and OSHA) and provide services under a quality system which meets the requirements of FDA QSR, EN/ISO 13485, and in alignment with EN ANSI/AAMI/ISO 11137. STERIS certifies that these processed items received the indicated doses within the precision and accuracy of the dosimetry system used. Legal Entity: Synergy Health Sterilisation UK, a STERIS Company.

Processing Location

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BD4 6SE
Phone: +44 (0) 1274-686011

Document ID: 48264

Advanced Medical Solutions Ltd

Advanced Medical Solutions Limited
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Web: www.admedsol.com
Registered in England 2666957 VAT No. GB 636 5551 27

Medicline D.O.O
Vinogradska 217
Osijek 31000
Croatia.

Date: 18th June 2025

CERTIFICATE OF CONFORMANCE

This is to certify that the product listed below has been manufactured and sterilised according to Advanced Medical Solutions specifications and procedures in compliance with Good Manufacturing Practice for Medical Devices. This product has been validated per ISO guidelines to provide a Sterilty Assurance Level of 10^{-6}.

All internal inspection and test requirements have been met. Test results are on file and available upon request.

Part Number	Description	Manufacturing Lot Number	Sterile Lot Number	Quantity (cartons)
10016986	Medicline Alginur Ag Silver Alginate Antimicrobial Wound Dressing 20x30cm Ref: 3012	W00076243	2163-12509A	1000 ctns

Customer Order Number: June 25

Prepared By:

Name: Ian Platt
Quality Assurance

Verified By:

Name: Sylwia Mikołajczak
Quality Assurance

LOT W00076243 18 JUN 2025.

STERIS: Gamma Certificate Of Processing

Prepared For ADVANCED MEDICAL SOLUTIONS LTD (8544)

Gamma Process Run ID 2163-12509A

Product Code	Lot Number	Quantity	UOM
PROCESSING FAMILY 1	Multiple	13	Pallet

Validation Reference Number: 1.0037

Processing Run Start Date 15-Jun-2025 1:39 AM

Processing Run End Date 15-Jun-2025 6:17 AM

Specified Dose Range (kGy)	**25.0 - 40.0**	**Calculated Min Dose (kGy)**	**27.1**
Reference Dose Range (kGy)	**31.7 - 36.6**	**Calculated Max Dose (kGy)**	**39.2**

PO Number 2051706

Product meets Customer specifications; zero nonconformities occurred during this irradiation run.

Other Information

QTY 1060 CASES + 3 SAMPLES, 76204/01, 76243/01/02, 76244/06/07, 76327/07/08/09/10, 76364/08/09/10/11

Gamma Process Run Approval authorized by STERIS

DateTime Esigned 17-Jun-2025 6:34 AM

Operating facilities is in compliance with applicable state and federal regulations (FDA, NRC, EPA, and OSHA) and provide services under a quality system which meets the requirements of FDA QSR, EN/ISO 13485, and in alignment with EN ANSI/AAMI/ISO 11137. STERIS certifies that these processed items received the indicated doses within the precision and accuracy of the dosimetry system used. Legal Entity: Synergy Health Sterilisation UK, a STERIS Company.

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Osijek 31000
Croatia.

Date: 24th June 2025

CERTIFICATE OF CONFORMANCE

This is to certify that the product listed below has been manufactured and sterilised according to Advanced Medical Solutions specifications and procedures in compliance with Good Manufacturing Practice for Medical Devices. This product has been validated per ISO guidelines to provide a Sterilty Assurance Level of 10^{-6}.

All internal inspection and test requirements have been met. Test results are on file and available upon request.

Part Number	Description	Manufacturing Lot Number	Sterile Lot Number	Quantity (cartons)
10017222	Medicline Nurocel Extra Ag Silver Fibrous Cellulose Antimicrobial Wound Dressing 20x30cm Ref: 8005	W00076333	2163-12533A	540 ctns

Customer Order Number: June 25

Prepared By:

Name: Christine Jones
Quality Assurance

Verified By:

Name: Ian Platt
Quality Assurance

LOT W0007633 20 JUN2025.

STERIS: Gamma Certificate Of Processing

Prepared For ADVANCED MEDICAL SOLUTIONS LTD (8544)

Gamma Process Run ID 2163-12533A

Product Code	Lot Number	Quantity	UOM
PROCESSING FAMILY 1	Multiple	16	Pallet

Validation Reference Number: 1.0037

Processing Run Start Date 16-Jun-2025 2:22 PM

Processing Run End Date 16-Jun-2025 9:50 PM

Specified Dose Range (kGy)	**25.0 - 40.0**	**Calculated Min Dose (kGy)**	**27.2**
Reference Dose Range (kGy)	**31.7 - 36.6**	**Calculated Max Dose (kGy)**	**39.5**

PO Number 2051706

Product meets Customer specifications; zero nonconformities occurred during this irradiation run.

Other Information

QTY 901 CASES + 12 SAMPLES, 75999/01/02, 76035/12, 76239/01, 76392/02, 76244/08/09, 76288/01,76325/01, 76326/01/02, 76333/01, 76363/02/03, 76364/12, 76372/01

Gamma Process Run Approval authorized by STERIS

DateTime Esigned 17-Jun-2025 3:39 PM

Operating facilities is in compliance with applicable state and federal regulations (FDA, NRC, EPA, and OSHA) and provide services under a quality system which meets the requirements of FDA QSR, EN/ISO 13485, and in alignment with EN ANSI/AAMI/ISO 11137. STERIS certifies that these processed items received the indicated doses within the precision and accuracy of the dosimetry system used. Legal Entity: Synergy Health Sterilisation UK, a STERIS Company.

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Date: 24th June 2025

CERTIFICATE OF CONFORMANCE

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All internal inspection and test requirements have been met. Test results are on file and available upon request.

Part Number	Description	Manufacturing Lot Number	Sterile Lot Number	Quantity (cartons)
10016983	Medicline Nurocel Extra Fibrous Cellulose Dressing HPD 20x20cm Ref: 2012	W00076326	2163-12533A	1000 ctns

Customer Order Number: June 25

Prepared By:

Name: Christine Jones
Quality Assurance

Verified By:

Name: Ian Platt
Quality Assurance

Certificate No. MD78010

W0076326 20 JUN 2025.

STERIS: Gamma Certificate Of Processing

Prepared For ADVANCED MEDICAL SOLUTIONS LTD (8544)

Gamma Process Run ID 2163-12533A

Product Code	Lot Number	Quantity	UOM
PROCESSING FAMILY 1	Multiple	16	Pallet

Validation Reference Number: 1.0037

Processing Run Start Date 16-Jun-2025 2:22 PM

Processing Run End Date 16-Jun-2025 9:50 PM

Specified Dose Range (kGy)	**25.0 - 40.0**	**Calculated Min Dose (kGy)**	**27.2**
Reference Dose Range (kGy)	**31.7 - 36.6**	**Calculated Max Dose (kGy)**	**39.5**

PO Number 2051706

Product meets Customer specifications; zero nonconformities occurred during this irradiation run.

Other Information

QTY 901 CASES + 12 SAMPLES, 75999/01/02, 76035/12, 76239/01, 76392/02, 76244/08/09, 76288/01,76325/01, 76326/01/02, 76333/01, 76363/02/03, 76364/12, 76372/01

Gamma Process Run Approval authorized by STERIS

DateTime Esigned 17-Jun-2025 3:39 PM

Operating facilities is in compliance with applicable state and federal regulations (FDA, NRC, EPA, and OSHA) and provide services under a quality system which meets the requirements of FDA QSR, EN/ISO 13485, and in alignment with EN ANSI/AAMI/ISO 11137. STERIS certifies that these processed items received the indicated doses within the precision and accuracy of the dosimetry system used. Legal Entity: Synergy Health Sterilisation UK, a STERIS Company.

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Croatia.

Date: 24th June 2025

CERTIFICATE OF CONFORMANCE

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All internal inspection and test requirements have been met. Test results are on file and available upon request.

Part Number	Description	Manufacturing Lot Number	Sterile Lot Number	Quantity (cartons)
10016998	Medicline Nurofoam Sensitive Silicone Sacral Foam Dressing 18x18.5cm Ref: 6013	W00076365	IS33-9-160625-4	700 ctns

Customer Order Number: June 25

Prepared By:

Name: Christine Jones
Quality Assurance

Verified By:

Name: Ian Platt
Quality Assurance

Certificate No. MD78010

Lot W00076365 20 JUN 2025.

CERTIFICATE OF CONFORMANCE

FOR ETHYLENE OXIDE PROCESSING

GENERAL	
Andersen Caledonia Ethylene Oxide Pattern	10102
Customer	AMS Winsford
Andersen Caledonia Batch Number	IS33-9-160625-4
Customer Reference Numbers	PO 2051335 SP160625-6 x 8 Pallets Part No:10016998 Lot: W00076365 x 30 (01) Part No:10016998 Lot: W00076365 x 30 (02) Part No:10017196 Lot: W00076366 x 63 (01) Part No:10017196 Lot: W00076366 x 63 (02)
Sterilisation Process Completion Date	18th June 2025
Additional Information	Load Temperature Specification: ≥ 7°C on arrival. Actual: 17.1°C

N.B Sterilisation process complete = heated aeration is complete
See checklist for all process parameters

AERATION PROCESS

PARAMETER	SPECIFICATION	ACTUAL
Heated Aeration temperature	36 - 46°C	Minimum – Maximum 37 – 42.7
Heated Aeration dwell time	24 to 72 hours	24.00

Customer ambient aeration requirement	N/A
Date and time ambient aeration complete	N/A
Where applicable - Goods should not be opened and are not fit for use until the stated ambient aeration date and time is completed.	

BIOLOGICAL INDICATOR TESTING

Biological indicator species used	*Bacillus atrophaeus*
Number of Biological Indicators used	22
Biological Indicator batch number	G251
Number of endospores per Biological Indicator	Minimum 1.0×10^6
Positive and negative controls satisfactory	Yes
Biological indicator cultures clear after 2 Days (procedure 4047)	Yes
Biological Indicator process dates	17/06/25 to 19/06/25

Biological indicators meet the requirements of ISO 11138 and minimum requirements of ISO 11135

The product referenced, as described by the Customer, was processed at Andersen Caledonia using Ethylene Oxide.
The process met the specification for validated cycle 10102

Approved by: Date: 20 JUN 2025

Andersen Caledonia Limited, Caledonian House, Phoenix Crescent, Strathclyde Business Park, Lanarkshire, ML4 3NJ, Scotland, United Kingdom.
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CERTIFICATE OF CONFORMANCE

FOR ETHYLENE OXIDE PROCESSING

GENERAL	
Andersen Caledonia Ethylene Oxide Pattern	10102
Customer	AMS Winsford
Andersen Caledonia Batch Number	IS33-9-160625-4
Customer Reference Numbers	PO 2051335 SP160625-6 x 8 Pallets Part No:10016991 Lot: W00076224 x 30 (01) Part No:10016991 Lot: W00076224 x 21 (02) Part No:10017196 Lot: W00076366 x 15 (03) Part No:10016998 Lot: W00076365 x 11 (03)
Sterilisation Process Completion Date	18th June 2025
Additional Information	Load Temperature Specification: ≥ 7°C on arrival. Actual: 17.1°C

N.B Sterilisation process complete = heated aeration is complete
See checklist for all process parameters

AERATION PROCESS

PARAMETER	SPECIFICATION	ACTUAL
Heated Aeration temperature	36 - 46°C	Minimum – Maximum 37 – 42.7
Heated Aeration dwell time	24 to 72 hours	24.00

Customer ambient aeration requirement	N/A
Date and time ambient aeration complete	N/A
Where applicable - Goods should not be opened and are not fit for use until the stated ambient aeration date and time is completed.	

BIOLOGICAL INDICATOR TESTING

Biological indicator species used	*Bacillus atrophaeus*
Number of Biological Indicators used	22
Biological Indicator batch number	G251
Number of endospores per Biological Indicator	Minimum 1.0×10^6
Positive and negative controls satisfactory	Yes
Biological indicator cultures clear after 2 Days (procedure 4047)	Yes
Biological Indicator process dates	17/06/25 to 19/06/25

Biological indicators meet the requirements of ISO 11138 and minimum requirements of ISO 11135

The product referenced, as described by the Customer, was processed at Andersen Caledonia using Ethylene Oxide.
The process met the specification for validated cycle 10102

Approved by: Date: 20 JUN 2025

Andersen Caledonia Limited, Caledonian House, Phoenix Crescent, Strathclyde Business Park, Lanarkshire, ML4 3NJ, Scotland, United Kingdom
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Osijek 31000
Croatia.

Date: 24th June 2025

CERTIFICATE OF CONFORMANCE

This is to certify that the product listed below has been manufactured and sterilised according to Advanced Medical Solutions specifications and procedures in compliance with Good Manufacturing Practice for Medical Devices. This product has been validated per ISO guidelines to provide a Sterilty Assurance Level of 10^{-6}.

All internal inspection and test requirements have been met. Test results are on file and available upon request.

Part Number	Description	Manufacturing Lot Number	Sterile Lot Number	Quantity (cartons)
10016991	Medicline Nurofoam Adhesive Foam Dressing 20x20cm Ref: 5012	W00076224	IS33-9-160625-4	500 ctns

Customer Order Number: June 25

Prepared By:

Name: Christine Jones
Quality Assurance

Verified By:

Name: Ian Platt
Quality Assurance

LOT W00076224 20 JUN 2025.

ANDERSEN CALEDONIA

CERTIFICATE OF CONFORMANCE

FOR ETHYLENE OXIDE PROCESSING

GENERAL	
Andersen Caledonia Ethylene Oxide Pattern	10102
Customer	AMS Winsford
Andersen Caledonia Batch Number	IS33-9-160625-4
Customer Reference Numbers	PO 2051335 SP160625-6 x 8 Pallets Part No:10016998 Lot: W00076365 x 30 (01) Part No:10016998 Lot: W00076365 x 30 (02) Part No:10017196 Lot: W00076366 x 63 (01) Part No:10017196 Lot: W00076366 x 63 (02)
Sterilisation Process Completion Date	18th June 2025
Additional Information	Load Temperature Specification: ≥ 7°C on arrival. Actual: 17.1°C

N.B Sterilisation process complete = heated aeration is complete
See checklist for all process parameters

AERATION PROCESS

PARAMETER	SPECIFICATION	ACTUAL
Heated Aeration temperature	36 - 46°C	Minimum – Maximum 37 – 42.7
Heated Aeration dwell time	24 to 72 hours	24.00

Customer ambient aeration requirement	N/A
Date and time ambient aeration complete	N/A
Where applicable - Goods should not be opened and are not fit for use until the stated ambient aeration date and time is completed.	

BIOLOGICAL INDICATOR TESTING

Biological indicator species used	*Bacillus atrophaeus*
Number of Biological Indicators used	22
Biological Indicator batch number	G251
Number of endospores per Biological Indicator	Minimum 1.0 x 10^6
Positive and negative controls satisfactory	Yes
Biological indicator cultures clear after 2 Days (procedure 4047)	Yes
Biological Indicator process dates	17/06/25 to 19/06/25

Biological indicators meet the requirements of ISO 11138 and minimum requirements of ISO 11135

The product referenced, as described by the Customer, was processed at Andersen Caledonia using Ethylene Oxide.
The process met the specification for validated cycle 10102

Approved by: Date: 20 JUN 2025

Andersen Caledonia Limited, Caledonian House, Phoenix Crescent, Strathclyde Business Park, Lanarkshire, ML4 3NJ, Scotland, United Kingdom.
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Medicline D.O.O
Vinogradska 217
Osijek 31000
Croatia.

Date: 24th June 2025

CERTIFICATE OF CONFORMANCE

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All internal inspection and test requirements have been met. Test results are on file and available upon request.

Part Number	Description	Manufacturing Lot Number	Sterile Lot Number	Quantity (cartons)
10017221	Medicline Nurocel Extra Ag Silver Fibrous Cellulose Antimicrobial Wound Dressing 15x15cm Ref: 8004	W00076374	2163-12510A	1000 ctns

Customer Order Number: June 25

Prepared By:

Name: Christine Jones
Quality Assurance

Verified By:

Name: Ian Platt
Quality Assurance

Certificate No. MD78010

LOT W0007637 4 17 JUN 2025.

STERIS: Gamma Certificate Of Processing

Prepared For ADVANCED MEDICAL SOLUTIONS LTD (8544)

Gamma Process Run ID 2163-12510A

Product Code	Lot Number	Quantity	UOM
Processing Family 2	W00076374/01	1	Pallet

Validation Reference Number: 1.0058

Processing Run Start Date 13-Jun-2025 6:37 PM

Processing Run End Date 13-Jun-2025 10:12 PM

Specified Dose Range (kGy)	**25.0 - 40.0**	**Calculated Min Dose (kGy)**	**27.4**
Reference Dose Range (kGy)	**32.1 - 36.4**	**Calculated Max Dose (kGy)**	**38.6**

PO Number 2051706

Product meets Customer specifications; zero nonconformities occurred during this irradiation run.

Other Information

QTY 100 CASES + 1 SAMPLE, 76374/01

Gamma Process Run Approval authorized by STERIS

DateTime Esigned 16-Jun-2025 6:42 AM

Operating facilities is in compliance with applicable state and federal regulations (FDA, NRC, EPA, and OSHA) and provide services under a quality system which meets the requirements of FDA QSR, EN/ISO 13485, and in alignment with EN ANSI/AAMI/ISO 11137. STERIS certifies that these processed items received the indicated doses within the precision and accuracy of the dosimetry system used. Legal Entity: Synergy Health Sterilisation UK, a STERIS Company.

Processing Location

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Document ID: 48372

Advanced Medical Solutions Ltd

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Medicline D.O.O
Vinogradska 217
Osijek 31000
Croatia.

Date: 24th June 2025

CERTIFICATE OF CONFORMANCE

This is to certify that the product listed below has been manufactured and sterilised according to Advanced Medical Solutions specifications and procedures in compliance with Good Manufacturing Practice for Medical Devices. This product has been validated per ISO guidelines to provide a Sterilty Assurance Level of 10^{-6}.

All internal inspection and test requirements have been met. Test results are on file and available upon request.

Part Number	Description	Manufacturing Lot Number	Sterile Lot Number	Quantity (cartons)
10016988	Medicline Nurofoam Surgical PHMB Silicone Foam Dressing 10x30cm Ref: 4010	W00076367	IS33-8-180625-4	460 ctns

Customer Order Number: June 25

Prepared By:

Name: Christine Jones
Quality Assurance

Verified By:

Name: Ian Platt
Quality Assurance

Lot 76367 24 JUN 2025

ANDERSEN CALEDONIA

CERTIFICATE OF CONFORMANCE

FOR ETHYLENE OXIDE PROCESSING

GENERAL	
Andersen Caledonia Ethylene Oxide Pattern	20102
Customer	AMS Winsford
Andersen Caledonia Batch Number	IS33-8-180625-4
Customer Reference Numbers	PO 2051335 SP180625-9 x 6 Pallets Part No:10015147 Lot: W00076368 x 30 (02) Part No:10015147 Lot: W00076368 x 30 (01) Part No:10015147 Lot: W00076368 x 11 (03) Part No:10016988 Lot: W00076367 x 30 (01) Part No:10015118 Lot: W00076375 x 30 (01) Part No:10016988 Lot: W00076367 x 17 (02)
Sterilisation Process Completion Date	22nd June 2025
Additional Information	Load Temperature Specification: ≥ 7°C on arrival. Actual: 18.1°C

N.B Sterilisation process complete = heated aeration is complete
See checklist for all process parameters

AERATION PROCESS

PARAMETER	SPECIFICATION	ACTUAL
Heated Aeration temperature	36 - 46°C	Minimum – Maximum 44.5 – 46
Heated Aeration dwell time	24 to 72 hours	44.11

Customer ambient aeration requirement	N/A
Date and time ambient aeration complete	N/A
Where applicable - Goods should not be opened and are not fit for use until the stated ambient aeration date and time is completed.	

BIOLOGICAL INDICATOR TESTING

Biological indicator species used	*Bacillus atrophaeus*
Number of Biological Indicators used	22
Biological Indicator batch number	G251
Number of endospores per Biological Indicator	Minimum 1.0×10^6
Positive and negative controls satisfactory	Yes
Biological indicator cultures clear after 2 Days (procedure 4047)	Yes
Biological Indicator process dates	21/06/25 to 23/06/25

Biological indicators meet the requirements of ISO 11138 and minimum requirements of ISO 11135

The product referenced, as described by the Customer, was processed at Andersen Caledonia using Ethylene Oxide.
The process met the specification for validated cycle 20102

This C of C is supplement to and supersedes the previous C of C issued to AMS Winsford on the 23rd June 2025.

Approved by: A Dewar Date: 24 JUN 2025

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Osijek 31000
Croatia.

Date: 24th June 2025

CERTIFICATE OF CONFORMANCE

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All internal inspection and test requirements have been met. Test results are on file and available upon request.

Part Number	Description	Manufacturing Lot Number	Sterile Lot Number	Quantity (cartons)
10016982	Medicline Nurocel Extra Fibrous Cellulose Dressing HPD 15x15cm Ref: 2011	W00076325	2163-12533A	1000 ctns

Customer Order Number: June 25

Prepared By:

Name: Christine Jones
Quality Assurance

Verified By:

Name: Ian Platt
Quality Assurance

LOT W0007632S 20 JUN 2025.

STERIS: Gamma Certificate Of Processing

Prepared For ADVANCED MEDICAL SOLUTIONS LTD (8544)

Gamma Process Run ID 2163-12533A

Product Code	Lot Number	Quantity	UOM
PROCESSING FAMILY 1	Multiple	16	Pallet

Validation Reference Number: 1.0037

Processing Run Start Date 16-Jun-2025 2:22 PM

Processing Run End Date 16-Jun-2025 9:50 PM

Specified Dose Range (kGy)	**25.0 - 40.0**	**Calculated Min Dose (kGy)**	**27.2**
Reference Dose Range (kGy)	**31.7 - 36.6**	**Calculated Max Dose (kGy)**	**39.5**

PO Number 2051706

Product meets Customer specifications; zero nonconformities occurred during this irradiation run.

Other Information

QTY 901 CASES + 12 SAMPLES, 75999/01/02, 76035/12, 76239/01, 76392/02, 76244/08/09, 76288/01,76325/01, 76326/01/02, 76333/01, 76363/02/03, 76364/12, 76372/01

Gamma Process Run Approval authorized by STERIS

DateTime Esigned 17-Jun-2025 3:39 PM

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Processing Location

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Registered in England 2666957 VAT No. GB 636 5551 27

Medicline D.O.O
Vinogradska 217
Osijek 31000
Croatia.

Date: 24th June 2025

CERTIFICATE OF CONFORMANCE

This is to certify that the product listed below has been manufactured and sterilised according to Advanced Medical Solutions specifications and procedures in compliance with Good Manufacturing Practice for Medical Devices. This product has been validated per ISO guidelines to provide a Sterilty Assurance Level of 10^{-6}.

All internal inspection and test requirements have been met. Test results are on file and available upon request.

Part Number	Description	Manufacturing Lot Number	Sterile Lot Number	Quantity (cartons)
10017220	Medicline Nurocel Extra Ag Silver Fibrous Cellulose Antimicrobial Wound Dressing 10x10cm Ref: 8003	W00076239	2163-12533A	500 ctns

Customer Order Number: June 25

Prepared By:

Name: Christine Jones
Quality Assurance

Verified By:

Name: Ian Platt
Quality Assurance

Certificate No. MD78010

Lot W0007623 4 20 JUN 2025.

STERIS: Gamma Certificate Of Processing

Prepared For ADVANCED MEDICAL SOLUTIONS LTD (8544)

Gamma Process Run ID 2163-12533A

Product Code	Lot Number	Quantity	UOM
PROCESSING FAMILY 1	Multiple	16	Pallet

Validation Reference Number: 1.0037

Processing Run Start Date 16-Jun-2025 2:22 PM

Processing Run End Date 16-Jun-2025 9:50 PM

Specified Dose Range (kGy)	**25.0 - 40.0**	**Calculated Min Dose (kGy)**	**27.2**
Reference Dose Range (kGy)	**31.7 - 36.6**	**Calculated Max Dose (kGy)**	**39.5**

PO Number 2051706

Product meets Customer specifications; zero nonconformities occurred during this irradiation run.

Other Information

QTY 901 CASES + 12 SAMPLES, 75999/01/02, 76035/12, 76239/01, 76392/02, 76244/08/09, 76288/01,76325/01, 76326/01/02, 76333/01, 76363/02/03, 76364/12, 76372/01

Gamma Process Run Approval authorized by STERIS

DateTime Esigned 17-Jun-2025 3:39 PM

Operating facilities is in compliance with applicable state and federal regulations (FDA, NRC, EPA, and OSHA) and provide services under a quality system which meets the requirements of FDA QSR, EN/ISO 13485, and in alignment with EN ANSI/AAMI/ISO 11137. STERIS certifies that these processed items received the indicated doses within the precision and accuracy of the dosimetry system used. Legal Entity: Synergy Health Sterilisation UK, a STERIS Company.

Processing Location

Roydsdale Way
Euroway Trading Estate
Bradford, West Yorkshire
BD4 6SE
Phone: +44 (0) 1274-686011

Advanced Medical Solutions Ltd

Advanced Medical Solutions Limited
Premier Park, 33 Road One
Winsford Industrial Estate
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

Medicline D.O.O
Vinogradska 217
Osijek 31000
Croatia.

Date: 27th June 2025

CERTIFICATE OF CONFORMANCE

This is to certify that the product listed below has been manufactured and sterilised according to Advanced Medical Solutions specifications and procedures in compliance with Good Manufacturing Practice for Medical Devices. This product has been validated per ISO guidelines to provide a Sterilty Assurance Level of 10^{-6}.

All internal inspection and test requirements have been met. Test results are on file and available upon request.

Part Number	Description	Manufacturing Lot Number	Sterile Lot Number	Quantity (cartons)
10016994	Medicline Nurofoam Non- Adhesive Foam Heel Dressing 18x12cm Ref: 5015	W00076223	2163-12614A	1504 ctns

Customer Order Number: June 25

Prepared By:

Name: Christine Jones
Quality Assurance

Verified By:

Name: Ian Platt
Quality Assurance

Certificate No. MD78010

W0007622 23 JUN 2025.

STERIS: Gamma Certificate Of Processing

Prepared For ADVANCED MEDICAL SOLUTIONS LTD (8544)

Gamma Process Run ID 2163-12614A

Product Code	Lot Number	Quantity	UOM
PROCESSING FAMILY 1	MULTIPLE	16	Pallet

Validation Reference Number: 1.0037

Processing Run Start Date 19-Jun-2025 11:02 PM

Processing Run End Date 20-Jun-2025 5:37 AM

Specified Dose Range (kGy)	**25.0 - 40.0**	**Calculated Min Dose (kGy)**	**26.6**
Reference Dose Range (kGy)	**31.7 - 36.6**	**Calculated Max Dose (kGy)**	**38.4**

PO Number 2051706

Product meets Customer specifications; zero nonconformities occurred during this irradiation run.

Other Information

QTY 1259 CASES + 8 SAMPLES, 76223/01/02/03/04/05/06, 76455/01, 76459/01/02, 76460/01/02, 76461/01, 76475/01, 76476/01, 76477/01, 76478/01

Gamma Process Run Approval authorized by STERIS

DateTime Esigned 20-Jun-2025 6:54 AM

Operating facilities is in compliance with applicable state and federal regulations (FDA, NRC, EPA, and OSHA) and provide services under a quality system which meets the requirements of FDA QSR, EN/ISO 13485, and in alignment with EN ANSI/AAMI/ISO 11137. STERIS certifies that these processed items received the indicated doses within the precision and accuracy of the dosimetry system used. Legal Entity: Synergy Health Sterilisation UK, a STERIS Company.

Processing Location

Roydsdale Way
Euroway Trading Estate
Bradford, West Yorkshire
BD4 6SE
Phone: +44 (0) 1274-686011