



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: 24th June 2024

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 Sterility 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	W00071171	2163-6093A 2163-6144A	970 ctns

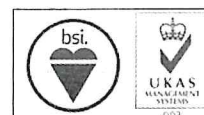
Customer Order Number: 24-0202-000001

Prepared By:


Name: Christine Jones
Quality Assurance

Verified By:


Name: Ian Platt
Quality Assurance



Lot 71171 *lf* 24 JUN 2024

STERIS: Gamma Certificate Of Processing

Prepared For ADVANCED MEDICAL SOLUTIONS LTD (8544)
Gamma Process Run ID 2163-6093A

Product Code	Lot Number	Quantity	UOM
PROCESSING FAMILY 1	FAMILY 1	8	Pallet
Validation Reference Number: 1.0037			

Processing Run Start Date 17-Jun-2024 1:52 AM
Processing Run End Date 17-Jun-2024 7:29 AM

Specified Dose Range (kGy)	25.0 - 40.0	Calculated Min Dose (kGy)	25.8
Reference Dose Range (kGy)	31.7 - 36.6	Calculated Max Dose (kGy)	38.6

PO Number 2050676

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

Other Information

QTY 470 CASES + 2 SAMPLES 71152/03/04/05, 71153/01/02, 71171/01, 71178/05/06

Gamma Process Run Approval authorized by STERIS
Date/Time Esigned 19-Jun-2024 6:50 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

Lot 71171  24 JUN 2024

STERIS: Gamma Certificate Of Processing

Prepared For ADVANCED MEDICAL SOLUTIONS LTD (8544)
Gamma Process Run ID 2163-6144A

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
PROCESSING FAMILY 1	Multiple Lots	6	Pallet
Validation Reference Number: 1.0037			

Processing Run Start Date 20-Jun-2024 5:28 AM

Processing Run End Date 20-Jun-2024 9:49 AM

Specified Dose Range (kGy)	25.0 - 40.0	Calculated Min Dose (kGy)	26.2
Reference Dose Range (kGy)	31.7 - 36.6	Calculated Max Dose (kGy)	38.3

PO Number 2050676

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

Other Information

QTY 425 CASES + 4 SAMPLES 71171/02, 71153/03/04, 71154/01, 71234/01/02

Gamma Process Run Approval authorized by STERIS

DateTime Esigned 21-Jun-2024 9:48 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: 28147



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Croatia.

Date: 24th June 2024

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.

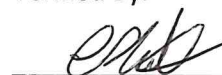
Part Number	Description	Manufacturing Lot Number	Sterile Lot Number	Quantity (cartons)
10016984	Medicline Alginur Ag Silver Alginate Antimicrobial Wound Dressing 10x10cm Ref: 3010	W00071054	2163-6078A	500 ctns

Customer Order Number: 24-0202-000001

Prepared By:


Name: Christine Jones
Quality Assurance

Verified By:


Name: Ian Platt
Quality Assurance



LOT 71054 *UP* 24 JUN 2024

STERIS: Gamma Certificate Of Processing

Prepared For ADVANCED MEDICAL SOLUTIONS LTD (8544)
Gamma Process Run ID 2163-6078A

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
PROCESSING FAMILY 1	MULTIPLE	23	Pallet
Validation Reference Number: 1.0037			

Processing Run Start Date 17-Jun-2024 5:10 AM

Processing Run End Date 17-Jun-2024 1:29 PM

Specified Dose Range (kGy)	25.0 - 40.0	Calculated Min Dose (kGy)	26.1
Reference Dose Range (kGy)	31.7 - 36.6	Calculated Max Dose (kGy)	38.9

PO Number 2050676

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

Other Information

QTY 1941 CASES + 12 SAMPLES - 70989/01, 71054/01, 71060/01/02, 71073/01, 71077/05, 71152/01/02, 71158/01/02, 71159/01/02, 71161/06, 71168/01, 71169/01, 71170/01, 71175/03/04/05, 71178/01/02/03/04

Gamma Process Run Approval authorized by STERIS

DateTime Esigned 19-Jun-2024 6:50 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: 27963



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Date: 24th June 2024

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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)
10016996	Medicline Nurofoam Sensitive Silicone Border Foam Dressing 15x15cm Ref: 6011	W00071004	IS33-9-040624-1	500 ctns

Customer Order Number: 24-0202-000001

Prepared By:

Name: Christine Jones
Quality Assurance

Verified By:

Name: Ian Platt
Quality Assurance



Lot 71004 12 JUN 2024



**ANDERSEN
CALEDONIA**

CERTIFICATE OF CONFORMANCE

FOR ETHYLENE OXIDE PROCESSING

GENERAL	
Andersen Caledonia Ethylene Oxide Pattern	10102
Customer	AMS Winsford
Andersen Caledonia Batch Number	IS33-9-040624-1
Customer Reference Numbers	PO 2048727 SP040624-3 x 3 Pallets Part No:10016996 Lot: W00071004 x 25 (01) Part No:10016996 Lot: W00071004 x 27 (02) Part No:10015122 Lot: W00071003 x 54 (01)
Sterilisation Process Completion Date	07 th June 2024
Additional Information	Load Temperature Specification: $\geq 7^{\circ}\text{C}$ on arrival. Actual: 17.1 $^{\circ}\text{C}$

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 $^{\circ}\text{C}$	40.5 - 41.7
Heated Aeration dwell time	08.00 - 72.00 hrs	08.04

Customer ambient aeration requirement	N/A
Date and time ambient aeration complete	N/A

When applicable - Goods should not be opened and are not fit for use until the stated aeration date and time is completed.

BIOLOGICAL INDICATOR TESTING

Biological indicator species used	<i>Bacillus atrophaeus</i>
Number of Biological Indicators used	22
Biological Indicator batch number	G243
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	07/06/24 to 09/06/24

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:

11 JUN 2024

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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Croatia.

Date: 26th June 2024

CERTIFICATE OF CONFORMANCE

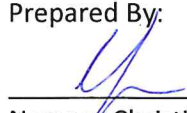
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All internal inspection and test requirements have been met. Test results are on file and available upon request.

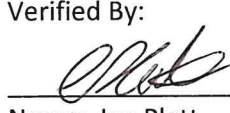
Part Number	Description	Manufacturing Lot Number	Sterile Lot Number	Quantity (cartons)
10017088	Medicline Nurofoam PHMB Non-Adhesive Foam Dressing 10x20cm Ref: 7010	W00071166	IS33-9-200624-3	500 ctns

Customer Order Number: 24-0202-000001

Prepared By:


Name: Christine Jones
Quality Assurance

Verified By:


Name: Ian Platt
Quality Assurance



Lot 71166 25 JUN 2024



ANDERSEN
CALEDONIA

CERTIFICATE OF CONFORMANCE

FOR ETHYLENE OXIDE PROCESSING

GENERAL	
Andersen Caledonia Ethylene Oxide Pattern	10102
Customer	AMS Winsford
Andersen Caledonia Batch Number	IS33-9-200624-3
Customer Reference Numbers	PO 2051142
	SP200624-9 x 6 Pallets
	Part No:10017089 Lot: W00071167 x 21 (02)
	Part No:10017089 Lot: W00071167 x 30 (01)
	Part No:10017088 Lot: W00071166 x 51 (01)
	Part No:10016473 Lot: W00071261 x 38 (02)
	Part No:10016987 Lot: W00071163 x 30 (01)
	Part No:10016987 Lot: W00071163 x 22 (02)
Sterilisation Process Completion Date	21 st June 2024
Additional Information	Load Temperature Specification: $\geq 7^{\circ}\text{C}$ on arrival. Actual: 18.2°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	38.3 - 42.3
Heated Aeration dwell time	08.00 - 72.00 hrs	09.35

Customer ambient aeration requirement	N/A
Date and time ambient aeration complete	N/A

When applicable - Goods should not be opened and are not fit for use until the stated aeration date and time is completed.

BIOLOGICAL INDICATOR TESTING

Biological indicator species used	<i>Bacillus atrophaeus</i>
Number of Biological Indicators used	22
Biological Indicator batch number	G243
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	21/06/24 to 23/06/24

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: 24 JUN 2024

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



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Date: 26th June 2024

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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)
10017089	Medicline Nurofoam PHMB Non-Adhesive Foam Dressing 20x20cm Ref: 7011	W00071167	IS33-9-200624-3	500 ctns

Customer Order Number: 24-0202-000001

Prepared By:


Name: Christine Jones
Quality Assurance

Verified By:


Name: Ian Platt
Quality Assurance



Lot 71167 25 JUN 2024



ANDERSEN
CALEDONIA

CERTIFICATE OF CONFORMANCE

FOR ETHYLENE OXIDE PROCESSING

GENERAL	
Andersen Caledonia Ethylene Oxide Pattern	10102
Customer	AMS Winsford
Andersen Caledonia Batch Number	IS33-9-200624-3
Customer Reference Numbers	PO 2051142 SP200624-9 x 6 Pallets Part No:10017089 Lot: W00071167 x 21 (02) Part No:10017089 Lot: W00071167 x 30 (01) Part No:10017088 Lot: W00071166 x 51 (01) Part No:10016473 Lot: W00071261 x 38 (02) Part No:10016987 Lot: W00071163 x 30 (01) Part No:10016987 Lot: W00071163 x 22 (02)
Sterilisation Process Completion Date	21 st June 2024
Additional Information	Load Temperature Specification: $\geq 7^{\circ}\text{C}$ on arrival. Actual: 18.2°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	38.3 – 42.3
Heated Aeration dwell time	08.00 – 72.00 hrs	09.35

Customer ambient aeration requirement	N/A
Date and time ambient aeration complete	N/A

When applicable - Goods should not be opened and are not fit for use until the stated aeration date and time is completed.

BIOLOGICAL INDICATOR TESTING

Biological indicator species used	<i>Bacillus atrophaeus</i>
Number of Biological Indicators used	22
Biological Indicator batch number	G243
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	21/06/24 to 23/06/24

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: 24 JUN 2024

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

Date: 26th June 2024

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

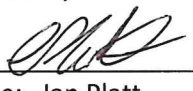
Part Number	Description	Manufacturing Lot Number	Sterile Lot Number	Quantity (cartons)
10016985	Medicline Alginur Ag Silver Alginate Antimicrobial Wound Dressing 15x15cm Ref: 3011	W00071059	2163-6145A	500 ctns

Customer Order Number: 24-0202-000001

Prepared By:


Name: Christine Jones
Quality Assurance

Verified By:


Name: Ian Platt
Quality Assurance



Lot 71059 26 JUN 2024

STERIS: Gamma Certificate Of Processing

Prepared For ADVANCED MEDICAL SOLUTIONS LTD (8544)
Gamma Process Run ID 2163-6145A

Product Code	Lot Number	Quantity	UOM
Processing Family 2	W00071059	1	Pallet
Validation Reference Number: 1.0058			

Processing Run Start Date 19-Jun-2024 6:33 PM

Processing Run End Date 19-Jun-2024 10:00 PM

Specified Dose Range (kGy)	25.0 - 40.0	Calculated Min Dose (kGy)	26.6
Reference Dose Range (kGy)	32.1 - 36.4	Calculated Max Dose (kGy)	37.5

PO Number 2050676

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

Other Information

QTY 50 CASES + 1 SAMPLE 71059/01

Gamma Process Run Approval authorized by STERIS
DateTime Esigned 20-Jun-2024 4:11 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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Osijek 31000
Croatia.

Date: 26th June 2024

CERTIFICATE OF CONFORMANCE

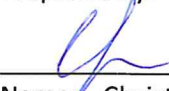
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All internal inspection and test requirements have been met. Test results are on file and available upon request.

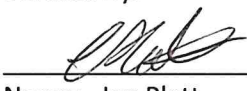
Part Number	Description	Manufacturing Lot Number	Sterile Lot Number	Quantity (cartons)
10016987	Medicline Nurofoam PHMB Silicone Sacral Foam Dressing 18.5x19.5cm Ref: 4011	W00071163	IS33-9-200624-3	500 ctns

Customer Order Number: 24-0202-000001

Prepared By:


Name: Christine Jones
Quality Assurance

Verified By:


Name: Ian Platt
Quality Assurance



LOT 71163 25 JUN 2024



ANDERSEN
CALEDONIA

CERTIFICATE OF CONFORMANCE

FOR ETHYLENE OXIDE PROCESSING

GENERAL	
Andersen Caledonia Ethylene Oxide Pattern	10102
Customer	AMS Winsford
Andersen Caledonia Batch Number	IS33-9-200624-3
Customer Reference Numbers	PO 2051142 SP200624-9 x 6 Pallets Part No:10017089 Lot: W00071167 x 21 (02) Part No:10017089 Lot: W00071167 x 30 (01) Part No:10017088 Lot: W00071166 x 51 (01) Part No:10016473 Lot: W00071261 x 38 (02) Part No:10016987 Lot: W00071163 x 30 (01) Part No:10016987 Lot: W00071163 x 22 (02)
Sterilisation Process Completion Date	21 st June 2024
Additional Information	Load Temperature Specification: $\geq 7^{\circ}\text{C}$ on arrival. Actual: 18.2 $^{\circ}\text{C}$

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 $^{\circ}\text{C}$	38.3 - 42.3
Heated Aeration dwell time	08.00 - 72.00 hrs	09.35

Customer ambient aeration requirement	N/A
Date and time ambient aeration complete	N/A

When applicable - Goods should not be opened and are not fit for use until the stated aeration date and time is completed.

BIOLOGICAL INDICATOR TESTING

Biological indicator species used	<i>Bacillus atrophaeus</i>
Number of Biological Indicators used	22
Biological Indicator batch number	G243
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	21/06/24 to 23/06/24

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: 24 JUN 2024

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