



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: 16th April 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 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)
10016985	Medicline Alginur Ag Silver Alginate Antimicrobial Wound Dressing 15x15cm Ref: 3011	W00075188	2163-11361A	950 ctns

Customer Order Number: Borna Mitonovic

Prepared By:

Name: Christine Jones
Quality Assurance

Verified By:

Name: Ian Platt
Quality Assurance



Lot 75188  15 APR 2025

STERIS: Gamma Certificate Of Processing

Prepared For ADVANCED MEDICAL SOLUTIONS LTD (8544)
Gamma Process Run ID 2163-11361A

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
Processing Family 2	W00075188	1	Pallet
Validation Reference Number: 1.0058			

Processing Run Start Date 12-Apr-2025 11:08 AM

Processing Run End Date 12-Apr-2025 2:38 PM

Specified Dose Range (kGy)	25.0 - 40.0	Calculated Min Dose (kGy)	26.9
Reference Dose Range (kGy)	32.1 - 36.4	Calculated Max Dose (kGy)	37.9

PO Number 2051706

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

Other Information

QTY 95 CASES + 1 SAMPLES , 75188/01

Gamma Process Run Approval authorized by STERIS

DateTime Esigned 14-Apr-2025 4:31 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

Document ID: 44951



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

Date: 25th April 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 Sterility Assurance Level of 10^{-6} .

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

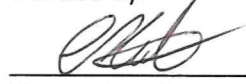
Part Number	Description	Manufacturing Lot Number	Sterile Lot Number	Quantity (cartons)
10016999	Medicline Nurofoam Sensitive Silicone Non-Border Foam Dressing 20x20cm Ref: 6014	W00075236	IS33-8-150425-2 ISAC-9-140425-2	1000 ctns

Customer Order Number: Borna Mitonovic

Prepared By:


Name: Christine Jones
Quality Assurance

Verified By:


Name: Ian Platt
Quality Assurance



Lot 75236 23 APR 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-9-140425-2
Customer Reference Numbers	PO 2051335 SP140425-10 x 9 Pallets Part No:10016995 Lot: W00075234 x 63 (01) Part No:10016995 Lot: W00075234 x 38 (02) Part No:10016997 Lot: W00075235 x 30 (01) Part No:10016997 Lot: W00075235 x 30 (02)
Sterilisation Process Completion Date	17 th April 2025
Additional Information	Load Temperature Specification: $\geq 7^{\circ}\text{C}$ on arrival. Actual: 18.4°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 40.4 – 43
Heated Aeration dwell time	08 to 72 hours	08.00

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	<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	16/04/25 to 19/04/25

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

This C of C is supplement to and supersedes the previous C of C issued to AMS Winsford on the 22nd April 2025.

Approved by:

Date:

23 APR 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



ANDERSEN
CALEDONIA

CERTIFICATE OF CONFORMANCE
FOR ETHYLENE OXIDE PROCESSING

GENERAL	
Andersen Caledonia Ethylene Oxide Pattern	10102
Customer	AMS Winsford
Andersen Caledonia Batch Number	ISAC-9-140425-2
Customer Reference Numbers	PO 2051335 SP140425-10 x 9 Pallets Part No:10016997 Lot: W00075235 x 30 (03) Part No:10016999 Lot: W00075236 x 30 (02) Part No:10016999 Lot: W00075236 x 30 (01) Part No:10016999 Lot: W00075236 x 30 (03) Part No:10017088 Lot: W00075391 x 50 (01)
Sterilisation Process Completion Date	17 th April 2025
Additional Information	Load Temperature Specification: $\geq 7^{\circ}\text{C}$ on arrival. Actual: 18.4°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 40.4 – 43
Heated Aeration dwell time	08 to 72 hours	08.00

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	<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	16/04/25 to 19/04/25

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: 22 APR 2025

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

Lot 75236 *lf* 22 APR 2025



ANDERSEN
CALEDONIA

CERTIFICATE OF CONFORMANCE

FOR ETHYLENE OXIDE PROCESSING

GENERAL	
Andersen Caledonia Ethylene Oxide Pattern	20102
Customer	AMS Winsford
Andersen Caledonia Batch Number	IS33-8-150425-2
Customer Reference Numbers	PO 2051335 SP140425-10 x 1 Pallet Part No:10016999 Lot: W00075236 x 11 (04)
Sterilisation Process Completion Date	17 th April 2025
Additional Information	Load Temperature Specification: $\geq 7^{\circ}\text{C}$ on arrival. Actual: 18.1 $^{\circ}\text{C}$

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 $^{\circ}\text{C}$	Minimum – Maximum 39.9 – 44
Heated Aeration dwell time	08 to 72 hours	08.18

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	<i>Bacillus atrophaeus</i>
Number of Biological Indicators used	20
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	16/04/25 to 19/04/25

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:

Neelgiani

Date:

22 APR 2025

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

Date: 25th April 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 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)
10016995	Medicline Nurofoam Sensitive Silicone Border Foam Dressing 10x10cm Ref: 6010	W00075234	ISAC-9-140425-2	1000 ctns

Customer Order Number: Borna Mitonovic

Prepared By:


Name: Christine Jones
Quality Assurance

Verified By:


Name: Ian Platt
Quality Assurance



Lot 75234 23 APR 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-9-140425-2
Customer Reference Numbers	PO 2051335 SP140425-10 x 9 Pallets Part No:10016995 Lot: W00075234 x 63 (01) Part No:10016995 Lot: W00075234 x 38 (02) Part No:10016997 Lot: W00075235 x 30 (01) Part No:10016997 Lot: W00075235 x 30 (02)
Sterilisation Process Completion Date	17 th April 2025
Additional Information	Load Temperature Specification: $\geq 7^{\circ}\text{C}$ on arrival. Actual: 18.4°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 40.4 – 43
Heated Aeration dwell time	08 to 72 hours	08.00

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	<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	16/04/25 to 19/04/25

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

This C of C is supplement to and supersedes the previous C of C issued to AMS Winsford on the 22nd April 2025.

Approved by:

Date:

23 APR 2025

Andersen Caledonia Limited, Caledonian House, Phoenix Crescent, Strathclyde Business Park, Lanarkshire, ML4 3NJ, Scotland, United Kingdom.
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Date: 29th April 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 Sterility Assurance Level of 10^{-6} .

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

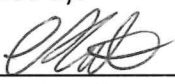
Part Number	Description	Manufacturing Lot Number	Sterile Lot Number	Quantity (cartons)
10016997	Medicline Nurofoam Sensitive Silicone Border Foam Dressing 20x20cm Ref: 6012	W00075235	ISAC-9-140425-2 IS33-9-170425-10	980 ctns

Customer Order Number: Borna Mitonovic

Prepared By:


Name: Christine Jones
Quality Assurance

Verified By:


Name: Ian Platt
Quality Assurance





ANDERSEN
CALEDONIA

CERTIFICATE OF CONFORMANCE

FOR ETHYLENE OXIDE PROCESSING

GENERAL	
Andersen Caledonia Ethylene Oxide Pattern	10102
Customer	AMS Winsford
Andersen Caledonia Batch Number	ISAC-9-140425-2
Customer Reference Numbers	PO 2051335 SP140425-10 x 9 Pallets Part No:10016995 Lot: W00075234 x 63 (01) Part No:10016995 Lot: W00075234 x 38 (02) Part No:10016997 Lot: W00075235 x 30 (01) Part No:10016997 Lot: W00075235 x 30 (02)
Sterilisation Process Completion Date	17 th April 2025
Additional Information	Load Temperature Specification: $\geq 7^{\circ}\text{C}$ on arrival. Actual: 18.4°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 40.4 – 43
Heated Aeration dwell time	08 to 72 hours	08.00

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	<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	16/04/25 to 19/04/25

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

This C of C is supplement to and supersedes the previous C of C issued to AMS Winsford on the 22nd April 2025.

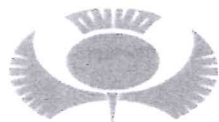
Approved by:

[Signature]

Date:

23 APR 2025

Lot 75235 28 APR 2025



ANDERSEN
CALEDONIA

CERTIFICATE OF CONFORMANCE

FOR ETHYLENE OXIDE PROCESSING

GENERAL	
Andersen Caledonia Ethylene Oxide Pattern	10102
Customer	AMS Winsford
Andersen Caledonia Batch Number	IS33-9-170425-10
Customer Reference Numbers	PO 2051335 SP170425-7 x 6 Pallets Part No:10017088 Lot: W00075391 x 51 (02) Part No:10017089 Lot: W00075493 x 20 (03) Part No:10016997 Lot: W00075235 x 9 (04) Part No:10017089 Lot: W00075493 x 30 (02) Part No:10017089 Lot: W00075493 x 30 (01) Part No:10017089 Lot: W00075493 x 9 (04)
Sterilisation Process Completion Date	24 th April 2025
Additional Information	Load Temperature Specification: $\geq 7^{\circ}\text{C}$ on arrival. Actual: 18.1 $^{\circ}\text{C}$

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 $^{\circ}\text{C}$	Minimum – Maximum 39.1 – 43.9
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	<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	23/04/25 to 26/04/25

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:

28 APR 2025



Advanced Medical Solutions Ltd

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Premier Park, 33 Road One
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Cheshire, CW7 3RT UK

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Osijek 31000
Croatia.

Date: 29th April 2025

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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	W00075493	IS33-9-170425-10	880 ctns

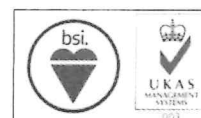
Customer Order Number: Borna Mitonovic

Prepared By:


Name: Christine Jones
Quality Assurance

Verified By:


Name: Ian Platt
Quality Assurance



Lot 75493 *lf* 28 APR 2025



ANDERSEN
CALEDONIA

CERTIFICATE OF CONFORMANCE

FOR ETHYLENE OXIDE PROCESSING

GENERAL	
Andersen Caledonia Ethylene Oxide Pattern	10102
Customer	AMS Winsford
Andersen Caledonia Batch Number	IS33-9-170425-10
Customer Reference Numbers	PO 2051335 SP170425-7 x 6 Pallets Part No:10017088 Lot: W00075391 x 51 (02) Part No:10017089 Lot: W00075493 x 20 (03) Part No:10016997 Lot: W00075235 x 9 (04) Part No:10017089 Lot: W00075493 x 30 (02) Part No:10017089 Lot: W00075493 x 30 (01) Part No:10017089 Lot: W00075493 x 9 (04)
Sterilisation Process Completion Date	24 th April 2025
Additional Information	Load Temperature Specification: $\geq 7^{\circ}\text{C}$ on arrival. Actual: 18.1 $^{\circ}\text{C}$

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 $^{\circ}\text{C}$	Minimum – Maximum 39.1 – 43.9
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	<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	23/04/25 to 26/04/25

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:

28 APR 2025



Advanced Medical Solutions Ltd

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Premier Park, 33 Road One

Winsford Industrial Estate

Cheshire, CW7 3RT UK

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Date: 29th April 2025

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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	W00075391	ISAC-9-140425-2 IS33-9-170425-10	1000 ctns

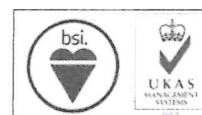
Customer Order Number: Borna Mitonovic

Prepared By:


Name: Christine Jones
Quality Assurance

Verified By:


Name: Ian Platt
Quality Assurance



Lot 75391 *4* 28 APR 2025



ANDERSEN
CALEDONIA

CERTIFICATE OF CONFORMANCE

FOR ETHYLENE OXIDE PROCESSING

GENERAL	
Andersen Caledonia Ethylene Oxide Pattern	10102
Customer	AMS Winsford
Andersen Caledonia Batch Number	IS33-9-170425-10
Customer Reference Numbers	PO 2051335 SP170425-7 x 6 Pallets Part No:10017088 Lot: W00075391 x 51 (02) Part No:10017089 Lot: W00075493 x 20 (03) Part No:10016997 Lot: W00075235 x 9 (04) Part No:10017089 Lot: W00075493 x 30 (02) Part No:10017089 Lot: W00075493 x 30 (01) Part No:10017089 Lot: W00075493 x 9 (04)
Sterilisation Process Completion Date	24 th April 2025
Additional Information	Load Temperature Specification: $\geq 7^{\circ}\text{C}$ on arrival. Actual: 18.1 $^{\circ}\text{C}$

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 $^{\circ}\text{C}$	Minimum – Maximum 39.1 – 43.9
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	<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	23/04/25 to 26/04/25

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:

28 APR 2025

Lot 75391 *lf* 23 APR 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-9-140425-2
Customer Reference Numbers	PO 2051335 SP140425-10 x 9 Pallets Part No:10016995 Lot: W00075234 x 63 (01) Part No:10016995 Lot: W00075234 x 38 (02) Part No:10016997 Lot: W00075235 x 30 (01) Part No:10016997 Lot: W00075235 x 30 (02)
Sterilisation Process Completion Date	17 th April 2025
Additional Information	Load Temperature Specification: $\geq 7^{\circ}\text{C}$ on arrival. Actual: 18.4 $^{\circ}\text{C}$

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 $^{\circ}\text{C}$	Minimum – Maximum 40.4 – 43
Heated Aeration dwell time	08 to 72 hours	08.00

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	<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	16/04/25 to 19/04/25

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

This C of C is supplement to and supersedes the previous C of C issued to AMS Winsford on the 22nd April 2025.

Approved by:

Signature

Date:

23 APR 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



ANDERSEN
CALEDONIA

CERTIFICATE OF CONFORMANCE FOR ETHYLENE OXIDE PROCESSING

GENERAL	
Andersen Caledonia Ethylene Oxide Pattern	10102
Customer	AMS Winsford
Andersen Caledonia Batch Number	ISAC-9-140425-2
Customer Reference Numbers	PO 2051335 SP140425-10 x 9 Pallets Part No:10016997 Lot: W00075235 x 30 (03) Part No:10016999 Lot: W00075236 x 30 (02) Part No:10016999 Lot: W00075236 x 30 (01) Part No:10016999 Lot: W00075236 x 30 (03) Part No:10017088 Lot: W00075391 x 50 (01)
Sterilisation Process Completion Date	17 th April 2025
Additional Information	Load Temperature Specification: $\geq 7^{\circ}\text{C}$ on arrival. Actual: 18.4°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 40.4 – 43
Heated Aeration dwell time	08 to 72 hours	08.00

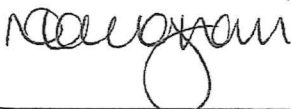
Customer ambient aeration requirement	N/A
Date and time ambient aeration complete	N/A
Where applicable - Goods should not be opened and are not fit for use until the stated ambient aeration date and time is completed.	

BIOLOGICAL INDICATOR TESTING

Biological indicator species used	<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	16/04/25 to 19/04/25

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: 22 APR 2025

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