



Advanced Medical Solutions Ltd

Advanced Medical Solutions Limited
Premier Park, 33 Road One
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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: 23rd May 2025

CERTIFICATE OF CONFORMANCE

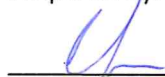
This is to certify that the product listed below has been manufactured and sterilised according to Advanced Medical Solutions specifications and procedures in compliance with Good Manufacturing Practice for Medical Devices. This product has been validated per ISO guidelines to provide a Sterility Assurance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

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

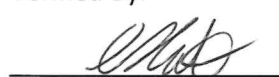
Part Number	Description	Manufacturing Lot Number	Sterile Lot Number	Quantity (cartons)
10017234	Medicline Nurofoam Sensitive PHMB Silicone Foam Border Dressing 20x20cm Ref: 4009	W00073499	IS33-9-200125-4	300 ctns

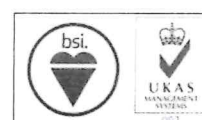
Customer Order Number: 24-0202-000004

Prepared By:


Name: Christine Jones
Quality Assurance

Verified By:


Name: Ian Platt
Quality Assurance



Lot 73499 23 JAN 2025



ANDERSEN
CALEDONIA

CERTIFICATE OF CONFORMANCE

FOR ETHYLENE OXIDE PROCESSING

GENERAL	
Andersen Caledonia Ethylene Oxide Pattern	10102
Customer	AMS Winsford
Andersen Caledonia Batch Number	IS33-9-200125-4
Customer Reference Numbers	PO 2051335 SP200125-9 x 4 Pallets Part No:10017234 Lot: W00073499 x 30 (01) Part No:10015836 Lot: W00073975 x 9 (01) Part No:10015835 Lot: W00073976 x 11 (01) Part No:10015146 Lot: W00073820 x 2 (01)
Sterilisation Process Completion Date	23 rd January 2025
Additional Information	Load Temperature Specification: $\geq 7^{\circ}\text{C}$ 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 36.8 – 42.4
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	23/01/25 to 25/01/25

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: 27 JAN 2025



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Date: 23rd May 2025

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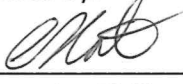
Part Number	Description	Manufacturing Lot Number	Sterile Lot Number	Quantity (cartons)
10017232	Medicline Nurofoam Surgical PHMB Silicone Foam Border Dressing 10x25cm Ref: 4007	W00073497	IS33-8-161224-1	400 ctns

Customer Order Number: 24-0202-000004

Prepared By:


Name: Christine Jones
Quality Assurance

Verified By:


Name: Ian Platt
Quality Assurance



Lot 73497 20 DEC 2024



ANDERSEN
CALEDONIA

CERTIFICATE OF CONFORMANCE

FOR ETHYLENE OXIDE PROCESSING

GENERAL	
Andersen Caledonia Ethylene Oxide Pattern	20102
Customer	AMS Winsford
Andersen Caledonia Batch Number	IS33-8-161224-1
Customer Reference Numbers	PO 2051335 SP161224-4 x 3 Pallets Part No:10015065 Lot: W00073568 x 30 (01) Part No:10017232 Lot: W00073497 x 41 (01) Part No:10015065 Lot: W00073568 x 30 (02)
Sterilisation Process Completion Date	17 th December 2024
Additional Information	Load Temperature Specification: $\geq 7^{\circ}\text{C}$ on arrival. Actual: 17.0°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	40.4 – 43.5
Heated Aeration dwell time	08.00 – 72.00 hrs	08.01

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	20
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	17/12/24 to 19/12/24

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 20102

Approved by:

Date: 20 DEC 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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Date: 23rd May 2025

CERTIFICATE OF CONFORMANCE

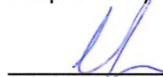
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All internal inspection and test requirements have been met. Test results are on file and available upon request.

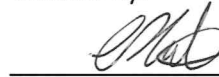
Part Number	Description	Manufacturing Lot Number	Sterile Lot Number	Quantity (cartons)
10017231	Medicline Nurofoam Surgical PHMB Silicone Foam Border Dressing 10x20cm Ref: 4006	W00073496	IS33-9-091224-2	410 ctns

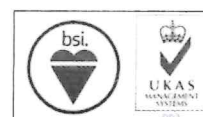
Customer Order Number: 24-0202-000004

Prepared By:


Name: Christine Jones
Quality Assurance

Verified By:


Name: Ian Platt
Quality Assurance



Lot 73496 13 DEC 2024



ANDERSEN
CALEDONIA

CERTIFICATE OF CONFORMANCE

FOR ETHYLENE OXIDE PROCESSING

GENERAL	
Andersen Caledonia Ethylene Oxide Pattern	10102
Customer	AMS Winsford
Andersen Caledonia Batch Number	IS33-9-091224-2
Customer Reference Numbers	PO 2051335 SP091224-10 x 3 Pallets Part No:10017233 Lot: W00073498 x 42 (01) Part No:10017233 Lot: W00073498 x 9 (02) Part No:10017231 Lot: W00073496 x 42 (01)
Sterilisation Process Completion Date	10 th December 2024
Additional Information	Load Temperature Specification: $\geq 7^{\circ}\text{C}$ on arrival. Actual: 16.2 $^{\circ}\text{C}$

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 $^{\circ}\text{C}$	Minimum – Maximum 36.8 – 41
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	10/12/24 to 12/12/24

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: 13 DEC 2024



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Date: 23rd May 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)
10017233	Medicline Nurofoam Sensitive PHMB Silicone Foam Border Dressing 15x15cm Ref: 4008	W00073498	IS33-9-091224-2	500 ctns

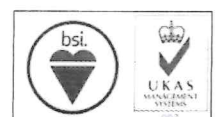
Customer Order Number: 24-0202-000004

Prepared By:

Name: Christine Jones
Quality Assurance

Verified By:

Name: Ian Platt
Quality Assurance



Lot 73498 13 DEC 2024



ANDERSEN
CALEDONIA

CERTIFICATE OF CONFORMANCE

FOR ETHYLENE OXIDE PROCESSING

GENERAL	
Andersen Caledonia Ethylene Oxide Pattern	10102
Customer	AMS Winsford
Andersen Caledonia Batch Number	IS33-9-091224-2
Customer Reference Numbers	PO 2051335 SP091224-10 x 3 Pallets Part No:10017233 Lot: W00073498 x 42 (01) Part No:10017233 Lot: W00073498 x 9 (02) Part No:10017231 Lot: W00073496 x 42 (01)
Sterilisation Process Completion Date	10 th December 2024
Additional Information	Load Temperature Specification: $\geq 7^{\circ}\text{C}$ on arrival. Actual: 16.2 $^{\circ}\text{C}$

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 $^{\circ}\text{C}$	Minimum - Maximum 36.8 - 41
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	10/12/24 to 12/12/24

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:

13 DEC 2024



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Date: 23rd May 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)
10017230	Medicline Nurofoam Sensitive PHMB Silicone Foam Border Dressing 10x10cm Ref: 4005	W00074459	ISAC-9-170225-5	160 ctns

Customer Order Number: 24-0202-000004

Prepared By:

Name: Christine Jones
Quality Assurance

Verified By:

Name: Ian Platt
Quality Assurance



Lot 74459 21 FEB 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-9-170225-5
Customer Reference Numbers	PO 2051335 SP170225-9 x 9 Pallets Part No:10015833 Lot: W00074458 x 30 (01) Part No:10015142 Lot: W00074457 x 18 (02) Part No:10017230 Lot: W00074459 x 17 (01) Part No:10015125 Lot: W00074053 x 11 (01)
Sterilisation Process Completion Date	18 th February 2025
Additional Information	Load Temperature Specification: $\geq 7^{\circ}\text{C}$ on arrival. Actual: 15.7°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 37.6 – 42.1
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	18/02/25 to 21/02/25

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: 21 FEB 2025