EC CERTIFICATE

Number: **66692CE01**

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding (4)
(Devices in Class IIa, IIb or III)

Manufacturer:

Gentherm Medical LLC

12011 Mosteller Road
Cincinnati, OH 45241
United States of America

For the product category(ies)

Electromedical Devices for Convective Air Therapy

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EC-Directive which apply to them:

0344

Documents that form the basis of this certificate:

Certification Notice 66692CN, initially dated 5 June 1997
Addendum, initially dated 3 June 2003

DEKRA hereby declares that the above-mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments. The manufacturer has implemented a quality assurance system for design, manufacture and final inspection for the above-mentioned product category in accordance to the provisions of Annex II of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance. For placing on the market of Class III devices an additional EC design examination certificate according to Annex II (4) is mandatory. The necessary information related to the quality management system of the manufacturer, including facilities and the reference to the relevant documentation of the products concerned and the assessments performed, are stated in the Certification Notice, which forms an integrative part of this certificate.

This certificate is valid until: **1 December 2023**
Issued for the first time: 5 June 1997
Revised: 23 April 2021
Reissued: 1 December 2018

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-product-safety.com Company registration 09085396

ADDENDUM

Belonging to certificate: **66692CE01**

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Electromedical Devices for Convective Air Therapy

Issued to:

Gentherm Medical LLC
12011 Mosteller Road
Cincinnati, OH 45241
United States of America

This certificate covers the following product(s):

WarmAir Units (Class IIb)

Initial date: 3 June 2003

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

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EC CERTIFICATE

Number: **66692CE02**

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding (4)
(Devices in Class IIa, IIb or III)

Manufacturer:

Gentherm Medical LLC

12011 Mosteller Road
Cincinnati, OH 45241
United States of America

For the product category(ies)

Electromedical Devices for Water-Based Hyper/Hypothermia Heater/Cooler Equipment

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EC-Directive which apply to them:

0344

Documents that form the basis of this certificate:

Certification Notice 66692CN, initially dated 5 June 1997
Addendum, initially dated 3 June 2003

DEKRA hereby declares that the above-mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments. The manufacturer has implemented a quality assurance system for design, manufacture and final inspection for the above-mentioned product category in accordance to the provisions of Annex II of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance. For placing on the market of Class III devices an additional EC design examination certificate according to Annex II (4) is mandatory. The necessary information related to the quality management system of the manufacturer, including facilities and the reference to the relevant documentation of the products concerned and the assessments performed, are stated in the Certification Notice, which forms an integrative part of this certificate.

This certificate is valid until: **1 December 2023**
Issued for the first time: 20 February 1998
Revised: 23 April 2021
Reissued: 1 December 2018
DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

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ADDENDUM

Belonging to certificate: **66692CE02**

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Electromedical Devices for Water-Based Hyper/Hypothermia Heater/Cooler Equipment

Issued to:

Gentherm Medical LLC
12011 Mosteller Road
Cincinnati, OH 45241
United States of America

This certificate covers the following product(s):

Water-Based Hyper/Hypothermia Units (Class IIb)

Initial date: 3 June 2003

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

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EC CERTIFICATE

Number: **66692CE03**

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding (4)
(Devices in Class IIa, IIb or III)

Manufacturer:

Gentherm Medical LLC

12011 Mosteller Road
Cincinnati, OH 45241
United States of America

For the product category(ies)

Air Hyper/Hypothermia Blankets

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EC-Directive which apply to them:

0344

Documents that form the basis of this certificate:

Certification Notice 66692CN, initially dated 5 June 1997
Addendum, initially dated 3 June 2003

DEKRA hereby declares that the above-mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments. The manufacturer has implemented a quality assurance system for design, manufacture and final inspection for the above-mentioned product category in accordance to the provisions of Annex II of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance. For placing on the market of Class III devices an additional EC design examination certificate according to Annex II (4) is mandatory. The necessary information related to the quality management system of the manufacturer, including facilities and the reference to the relevant documentation of the products concerned and the assessments performed, are stated in the Certification Notice, which forms an integrative part of this certificate.

This certificate is valid until: **1 December 2023**
Issued for the first time: 20 May 1998
Revised: 23 April 2021
Reissued: 1 December 2018

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

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ADDENDUM

Belonging to certificate: **66692CE03**

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Air Hyper/Hypothermia Blankets

Issued to:

Gentherm Medical LLC
12011 Mosteller Road
Cincinnati, OH 45241
United States of America

This certificate covers the following product(s):

Air Hyper/Hypothermia Blankets (Class IIb)

Initial date: 3 June 2003

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

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EC CERTIFICATE

Number: **66692CE04**

Full Quality Assurance System

Directive 93/42/EEC on Medical devices, Annex II excluding (4)
(Devices in Class IIa, IIb or III)

Manufacturer:

Gentherm Medical LLC
12011 Mosteller Road
Cincinnati, OH 45241
United States of America

For the product category(ies)

Water Hyper/Hypothermia Blankets

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EC-Directive which apply to them:

0344

Documents that form the basis of this certificate:

Certification Notice 66692CN, initially dated 5 June 1997
Addendum, initially dated 3 June 2003

DEKRA hereby declares that the above-mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments. The manufacturer has implemented a quality assurance system for design, manufacture and final inspection for the above-mentioned product category in accordance to the provisions of Annex II of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance. For placing on the market of Class III devices an additional EC design examination certificate according to Annex II (4) is mandatory. The necessary information related to the quality management system of the manufacturer, including facilities and the reference to the relevant documentation of the products concerned and the assessments performed, are stated in the Certification Notice, which forms an integrative part of this certificate.

This certificate is valid until: **1 December 2023**
Issued for the first time: 20 May 1998
Revised: 23 April 2021
Reissued: 1 December 2018

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

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ADDENDUM

Belonging to certificate: **66692CE04**

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Water Hyper/Hypothermia Blankets

Issued to:

Gentherm Medical LLC
12011 Mosteller Road
Cincinnati, OH 45241
United States of America

This certificate covers the following product(s):

Water Hyper/Hypothermia Blankets (Class IIb)

Initial date: 3 June 2003

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

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