

# 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:

### Cincinnati Sub-Zero Products, LLC

12011 Mosteller Road  
Cincinnati, OH 45241  
USA

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 June 5, 1997**  
**Addendum, initially dated June 3, 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 **December 1, 2018**  
Issued for the first time: **June 5, 1997**  
Revised: **May 10, 2016**

DEKRA Certification B.V.



drs. G.J. Zoetbrood  
Managing Director



ing. A.A.M. Laan  
Certification Manager

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

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T +31 88 96 83000 F +31 88 96 83100 [www.dekra-certification.com](http://www.dekra-certification.com) Company registration 09085396

# ADDENDUM

Belonging to certificate: 66692CE01

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## CE MARKING OF CONFORMITY MEDICAL DEVICES

Electromedical Devices for Convective Air Therapy

Issued to:

**Cincinnati Sub-Zero Products, LLC**  
12011 Mosteller Road  
Cincinnati, OH 45241  
USA

This certificate covers the following product(s):

WarmAir Units (Class IIb)

Initial date: June 3, 2003

DEKRA Certification B.V.

A handwritten signature in black ink, appearing to read "Zoetbrood".

drs. G.J. Zoetbrood  
Managing Director

A handwritten signature in black ink, appearing to read "A.A.M. Laan".

ing. A.A.M. Laan  
Certification Manager

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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:

### Cincinnati Sub-Zero Products, LLC

12011 Mosteller Road  
Cincinnati, OH 45241  
USA

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

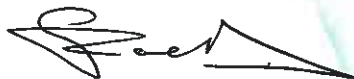
Documents that form the basis of this certificate:

**Certification Notice 66692CN, initially dated June 5, 1997**  
**Addendum, initially dated June 3, 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: **December 1, 2018**  
Issued for the first time: **February 20, 1998**  
Revised: **May 10, 2016**

DEKRA Certification B.V.



drs. G.J. Zoetbrood  
Managing Director



ing. A.A.M. Laan  
Certification Manager

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# ADDENDUM

Belonging to certificate: 66692CE02

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## CE MARKING OF CONFORMITY MEDICAL DEVICES

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

Issued to:

**Cincinnati Sub-Zero Products, LLC**

12011 Mosteller Road  
Cincinnati, OH 45241  
USA

This certificate covers the following product(s):

Water-Based Hyper/Hypothermia Units (Class IIb)

Initial date: June 3, 2003

DEKRA Certification B.V.

A handwritten signature in black ink, appearing to read "Zoetbrood".

drs. G.J. Zoetbrood  
Managing Director

A handwritten signature in black ink, appearing to read "A.A.M. Laan".

ing. A.A.M. Laan  
Certification Manager

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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:

### Cincinnati Sub-Zero Products, LLC

12011 Mosteller Road  
Cincinnati, OH 45241  
USA

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 June 5, 1997**  
**Addendum, initially dated June 3, 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: **December 1, 2018**

Issued for the first time: **May 20, 1998**

Revised: **May 10, 2016**

DEKRA Certification B.V.



drs. G.J. Zoetbrood  
Managing Director



ing. A.A.M. Laan  
Certification Manager

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# ADDENDUM

Belonging to certificate: 66692CE03

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## CE MARKING OF CONFORMITY MEDICAL DEVICES

**Air Hyper/Hypothermia Blankets**

Issued to:

**Cincinnati Sub-Zero Products, LLC**  
12011 Mosteller Road  
Cincinnati, OH 45241  
USA

This certificate covers the following product(s):

Air Hyper/Hypothermia Blankets (Class IIb)

Initial date: June 3, 2003

DEKRA Certification B.V.



drs. G.J. Zoetbrood  
Managing Director



ing. A.A.M. Laan  
Certification Manager

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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:

**Cincinnati Sub-Zero Products, LLC**

12011 Mosteller Road  
Cincinnati, OH 45241  
USA

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 June 5, 1997**  
**Addendum, initially dated June 3, 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: **December 1, 2018**  
Issued for the first time: **May 20, 1998**  
Revised: **May 10, 2016**

DEKRA Certification B.V.



drs. G.J. Zoetbrood  
Managing Director



ing. A.A.M. Laan  
Certification Manager

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# ADDENDUM

Belonging to certificate: 66692CE04

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## CE MARKING OF CONFORMITY MEDICAL DEVICES

**Water Hyper/Hypothermia Blankets**

Issued to:

**Cincinnati Sub-Zero Products, LLC**

12011 Mosteller Road  
Cincinnati, OH 45241  
USA

This certificate covers the following product(s):

Water Hyper/Hypothermia Blankets (Class IIb)

Initial date: June 3, 2003

DEKRA Certification B.V.

drs. G.J. Zoetbrood  
Managing Director

ing. A.A.M. Laan  
Certification Manager

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