

# CERTIFICATE

Number: 66692CE04



## CE MARKING OF CONFORMITY MEDICAL DEVICES

Issued to:

**Cincinnati Sub-Zero Products, Inc.**

12011 Mosteller Road  
Cincinnati, Ohio 45241-1528  
USA

For the product category:

**Water Hyper/Hypothermia Blankets**

KEMA 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**

KEMA hereby declares that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments, and that for the above mentioned product category the Conformity Assessment Procedure Annex II, section 3 for class II products, is executed by the Manufacturer in accordance with the provisions of the Council Directive 93/42/EEC of June 14, 1993. The necessary information 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, 2012**

Issued for the first time May 20, 1998

Renewal date: December 1, 2009

KEMA Quality B.V.



drs. G.J. Zoetbrood  
Managing Director



M. McCann  
Certification Manager

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**KEMA Medical**

KEMA Quality B.V. Utrechtseweg 310, 6812 AR Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands  
T +31 26 356 2000 F +31 26 352 5800 [www.kema.com](http://www.kema.com) Company registration 09085396

# 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, Inc.**

12011 Mosteller Road  
Cincinnati, Ohio 45241-1528  
USA

This certificate covers the following product(s):

Water Hyper/Hypothermia Blankets (Class IIb)

Initial date: June 3, 2003

KEMA Quality B.V.



drs. G.J. Zoelbrood  
Managing Director



M. McCann  
Certification Manager

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# CERTIFICATE

Number: 66692CE03



## CE MARKING OF CONFORMITY MEDICAL DEVICES

issued to:

**Cincinnati Sub-Zero Products, Inc.**

12011 Mosteller Road  
Cincinnati, Ohio 45241-1528  
USA

For the product category:

**Air Hyper/Hypothermia Blankets**

KEMA 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**

KEMA hereby declares that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments, and that for the above mentioned product category the Conformity Assessment Procedure Annex II, section 3 for class II products, is executed by the Manufacturer in accordance with the provisions of the Council Directive 93/42/EEC of June 14, 1993. The necessary information 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, 2012**  
Issued for the first time: May 20, 1998  
Renewal date: December 1, 2009

KEMA Quality B.V.



drs. G.J. Zoetbrood  
Managing Director



M. McCann  
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, Inc.**

12011 Mosteller Road  
Cincinnati, Ohio 45241-1528  
USA

This certificate covers the following product(s):

Air Hyper/Hypothermia Blankets (Class IIb)

Initial date: June 3, 2003

KEMA Quality B.V.



drs. G.J. Zoetbrood  
Managing Director



M. McCann  
Certification Manager

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# CERTIFICATE

Number: 66692CE02

## CE MARKING OF CONFORMITY MEDICAL DEVICES



Issued to:

**Cincinnati Sub-Zero Products, Inc.**

12011 Mosteller Road  
Cincinnati, Ohio 45241-1528  
USA

For the product category:

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

KEMA 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**

KEMA hereby declares that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments, and that for the above mentioned product category the Conformity Assessment Procedure Annex II, section 3 for class II products, is executed by the Manufacturer in accordance with the provisions of the Council Directive 93/42/EEC of June 14, 1993. The necessary information 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, 2012**  
issued for the first time: February 20, 1998  
Renewal date: December 1, 2009

KEMA Quality B.V.



drs. G.J. Zoetbrood  
Managing Director



M. McCann  
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, Inc.**

12011 Mosteller Road  
Cincinnati, Ohio 45241-1528  
USA

This certificate covers the following product(s):

Water-Based Hyper/Hypothermia Units (Class IIb)

Initial date: June 3, 2003

KEMA Quality B.V.

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

drs. G.J. Zoetbrood  
Managing Director

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

M. McCann  
Certification Manager

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# CERTIFICATE

Number: 66692CE01

## CE MARKING OF CONFORMITY MEDICAL DEVICES



Issued to:

**Cincinnati Sub-Zero Products, Inc.**

12011 Mosteller Road  
Cincinnati, Ohio 45241-1528  
USA

For the product category:

**Electromedical Devices for Convective Air Therapy**

KEMA 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**

KEMA hereby declares that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments, and that for the above mentioned product category the Conformity Assessment Procedure Annex II, section 3 for class II products, is executed by the Manufacturer in accordance with the provisions of the Council Directive 93/42/EEC of June 14, 1993. The necessary information 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, 2012**

Issued for the first time: June 5, 1997

Renewal date: December 1, 2009

KEMA Quality B.V.



drs. G.J. Zoetbrood  
Managing Director



M. McCann  
Certification Manager

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Experience you can trust.

# ADDENDUM

Belonging to certificate: 66692CE01

1/1

## CE MARKING OF CONFORMITY MEDICAL DEVICES

Electromedical Devices for Convective Air Therapy

Issued to:

**Cincinnati Sub-Zero Products, Inc.**

12011 Mosteller Road  
Cincinnati, Ohio 45241-1528  
USA

This certificate covers the following product(s):

WarmAir Units (Class IIb)

Initial date: June 3, 2003

KEMA Quality 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 "McCann".

M. McCann  
Certification Manager

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