A GENTHERM COMPANY	Document No.: DC-018	Rev. 4

DECLARATION OF CONFORMITY

Manufacturer:

Cincinnati Sub-Zero Products, LLC
12011 Mosteller Road
Cincinnati, Ohio 45241-1528

Warehouse:
7100 Dixie Highway
Fairfield, Ohio 45014

EC Representative:

CEpartner4U B.V.
Esdoornlaan 13
3951 DB Maarn
The Netherlands

Hereby declares that the products listed below fall within Class IIb and meet the provisions of the Medical Device Directive of the European Union, 93/42/EEC, as last amended under Directive 2007/42/EC. An examination of the Quality Management System has been carried out according to the conformity assessment procedure for CE-Marking in Annex II of the directive by Notified Body DEKRA Certification B.V., Notified Body EC No. 0344. The CSZ Quality Management System complies with ISO13485:2003.

Hereby declares that the products listed below are compliant to RoHS Directive 2011/65/EU of the European Parliament and the Council from 08/06/2011 on restriction of the use of certain hazardous substances in electrical and electronic equipment (EEE).

Product name	Description	Model number	CSZ Part #	First date of CE-marking
Hemotherm	Dual Reservoir Cooler/Heater System	400CE	86023	2009-02
Hemotherm Remote Control	Wired, Remotely – Located Controller	414CE	93816	2009-11
Connecting Hose	9' Reusable Connecting Hose	286	91824	1998-01
Connecting Hose	18' Reusable Connecting Hose	286-18	91840	1998-01
Connecting Hose	27' Reusable Connecting Hose	286-27	91841	1998-01

7/24/2018
Jamie Allen (Date)
Director of Engineering

7/23/18
Christina M. Miracle (Date)
Manager of Regulatory Compliance

Applied standards in full or in part:

Standard No.	Title
ISO 13485:2003	Medical Devices — Quality management systems — Requirements for regulatory purposes
EN ISO 14971:2012	Medical Devices- Application of Risk Management to Medical Devices
IEC 60601-1:2005; A1: 2012	Medical electrical equipment- Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2007	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests
IEC 60601-1-6:2010	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
IEC 80601-2-35:2009	Medical electrical equipment – Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads or mattresses and intended for heating in medical use
EN 1041:2008	Information supplied by the manufacturer of medical devices

References:

CE-Certificate Number: 66692CE02

CSZ Tech File Number: CETF- 400CE

DoC Release Date: 7/24/18

Revision History:

Rev. No.	Revision Description
Orig.	Initial declaration, previously on Form 0347.15.
1	Updated DoC from revised template from 0622.5 to 0622.6. Added First Date of CE Marking column and dates. Added Universal Mounting Clamp and Flow Indicator with Shut-off Valve Assembly to product list. Updated ISO 14971:2007 to ISO14971:2012 in the Applied Standards list. Added connecting hoses 91824, 91840, 91841 and 89186 to Product List.
2	Updated DoC form revised template from 0622.6 to 0622.7. Removed standard MEDDEV 2.7.1:2009. Replaced BS EN 980:2008 with ISO 15223:2012. Added AM1:2013 to BS EN 1041:2008.
3	Removed Universal Mounting Clamp (P/N 91811) from product list. Updated to current Template. Updated list of Applied Standards.
4	Updated DoC to new template, updated standards to reference EU's harmonized standards, removed irrelevant and superseded/withdrawn standards.

A GENTHERM COMPANY	Document No.: DC-013	Rev. 4

DECLARATION OF CONFORMITY

Manufacturer:

Cincinnati Sub-Zero Products, LLC
12011 Mosteller Road
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EC Representative:

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Esdoornlaan 13
3951 DB Maarn
The Netherlands

Warehouse:
7100 Dixie Highway
Fairfield, Ohio 45014

Hereby declares that the products listed below fall within Class IIb and meet the provisions of the Medical Device Directive of the European Union, 93/42/EEC, as last amended under Directive 2007/42/EC. An examination of the Quality Management System has been carried out according to the conformity assessment procedure for CE-Marking in Annex II of the directive by Notified Body DEKRA Certification B.V., Notified Body EC No. 0344. The CSZ Quality Management System complies with ISO13485:2003.

Hereby declares that the products listed below are compliant to RoHS Directive 2011/65/EU of the European Parliament and the Council from 08/06/2011 on restriction of the use of certain hazardous substances in electrical and electronic equipment (EEE).

Product name	Description	Model number	CSZ Part #	First date of CE-marking
Electri-Cool II 230/240V	Localized Cold Therapy System	767	86194	2004-01
Dual-Matic	Flow Rate and Temperature Tester	TF-100	86173	2005-09
Hose Assembly, 6 Ft.	Hose Assembly, 6 Ft. Insulated	757-H1E	71600	2015-12
Hose 8 Ft. Dual Pad	Hose Assembly, 6 Ft. Insulated	757-H8D	79723	2015-12
Hose 12 in. Dual Pad	Assembly, Hose 12 in. insulated Dual pad	757-H1D	79701	2015-12
Hose 24 in. Dual Pad	Assembly, Hose 24 in. Insulated Dual pad	757-H2D	79703	2015-12

1/24/2018
Jamie Allen (Date)
Director of Engineering

1/23/18
Christina M. Miracle (Date)
Manager of Regulatory Compliance

Applied standards in full or in part:

Standard No.	Title
ISO 13485:2003	Quality management systems - Requirements regulatory purposes
EN ISO 14971:2012	Medical Devices- Application of risk managment to medical devices
IEC 60601-1:2005: A1: 2012	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2007	Medical electrical equipment- Part 1-2: General requirements for safety-Collateral standard: Electromagnetic compatibility requirements and tests
IEC 60601-1-6:2010	Medical Electrical Equipment – General requirements for basic safety and essential performance - Collateral standard: Usability
EN 1041:2008	Information supplied by the manufacturer of medical devices

References:

CE-Certificate Number: 66692CE02

CSZ Tech File Number: CETF- 767

DoC Release Date: 7/24/18

Revision History:

Rev. No.	Revision Description
Orig.	Initial declaration
1	Updated DoC form revised template from 0622.3 to 0622.6. Added First Date of CE Marking column and dates. Added IEC 60601-1:1988, AM1:1991, AM2:1995 to Applied Standard list. Corrected IEC 60601-1-1:2005 to IEC 60601-1:2005 and IEC 60601-1-6:2007 to IEC 60601-1-6: 2010. Simplified the date for standard ISO 13485:2003. Updated standard ISO 14971:2007 to ISO 14971:2012.
2	Updated DoC form revised template from 0622.6 to 0622.7. Removed standard MEDDEV 2.7.1:2009. Replaced BS EN 980:2008 with ISO 15223:2012. Added AM1:2013 to BS EN 1041:2008.
3	Updated to current template. Added Hose Assembly, 6 Ft. (P/N 71600) and Hose 8 Ft., Dual Pad (P/N 79723) to product list. Updated list of applied standards.
4	Updated DoC to new template, updated standards to reference EU's harmonized standards, removed irrelevant and superseded/withdrawn standards.

A GENTHERM COMPANY	Document No.: DC-006	Rev. 4

DECLARATION OF CONFORMITY

Manufacturer:

Cincinnati Sub-Zero Products, LLC
12011 Mosteller Road
Cincinnati, Ohio 45241-1528

EC Representative:

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Esdoornlaan 13
3951 DB Maarn
The Netherlands

Warehouse:
7100 Dixie Highway
Fairfield, Ohio 45014

Hereby declares that the products listed below fall within Class IIb and meet the provisions of the Medical Device Directive of the European Union, 93/42/EEC, as last amended under Directive 2007/42/EC. An examination of the Quality Management System has been carried out according to the conformity assessment procedure for CE-Marking in Annex II of the directive by Notified Body DEKRA Certification B.V., Notified Body EC No. 0344. The CSZ Quality Management System complies with ISO13485:2003.

Hereby declares that the products listed below are compliant to RoHS Directive 2011/65/EU of the European Parliament and the Council from 08/06/2011 on restriction of the use of certain hazardous substances in electrical and electronic equipment (EEE).

Product name	Description	Model number	CSZ Part #	First date of CE-marking
Norm-O-Temp 111W	Hyperthermia System	111W	86158	1998-01
Norm-O-Temp Stand with IV Pole	Stand with IV Pole	118	52301	1998-01
Norm-O-Temp Low Profile Stand	Low Profile Stand	119	52302	1998-01
9' Reusable Hose	9' Reusable Connecting Hose	286	91824	1998-01
27' Reusable Hose Extension	27' Reusable Extension Hose	287-27	91831	2015-11
18' Reusable Hose	18' Reusable Connecting Hose	286-18	91840	1998-01
27' Reusable Hose	27' Reusable Connecting Hose	286-27	91841	1998-01

7/24/2018
Jamie Allen (Date)
Director of Engineering

7/23/18
Christina M. Miracle (Date)
Manager of Regulatory Compliance

Applied standards in full or in part:

Standard No.	Title
ISO 13485:2003	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2012	Medical Devices- Application of Risk Management to Medical Devices
IEC 60601-1:2005: A1: 2012	Medical electrical equipment – Part 1: general requirements for basic safety and essential performance.
EN 60601-1-2:2007	Medical electrical equipment- Part 1-2: General requirements for safety- Collateral standard: Electromagnetic compatibility requirements and tests
IEC 60601-1-6:2010	Medical Electrical Equipment – General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 80601-2-35: 2009	Medical electrical equipment: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads or mattresses and intended for heating in medical use
EN 1041:2008	Information supplied by the manufacturer of medical devices

References:

CE-Certificate Number: 66692CE02

CSZ Tech File Number: CETF- 111W

DoC Release Date: 7/24/18

Revision History:

Rev. No.	Revision Description
Orig.	Initial declaration. Previously Form #0347.15.
1	Updated DoC form revised template from 0622.5 to 0622.6. Added First Date of CE Marking column and dates. Added Norm-O-Temp Stand with IV Pole (118) and Low Profile Pole (119) to product list. Deleted IEC 60601-2:2007 from Applied Standards List. Updated standards IEC 60601-1-6:2007 to IEC 60601-1-6:2010, IEC 60601-1-2:2004 to IEC 60601-1-2:2007 and ISTA 1D:2001 to ISTA 1C:2001. Updated standard ISO 14971:2007 to ISO 14971:2012.
2	Updated reference to BS EN ISO 14971:2012 by adding the BS EN. Removed reference to MEDDEV 2.7.1:2009 Guidelines on Medical Devices – Clinical Evaluation. Updated reference from BS EN 980:2008 to ISO 15223-1:2012. Updated reference to BS EN 1041:2008 by adding AM1:2013. Updated DoC template from 0622.6 to 0622.7 which added the RoHS compliance statement.
3	Updated to current template. Added 27; Reusable Hose Extension (P/N 91831) to product list. Updated list of applied standards.
4	Updated DoC to new template, updated standards to reference EU's harmonized standards, removed irrelevant and superseded/withdrawn standards.

DECLARATION OF CONFORMITY

Manufacturer:

Cincinnati Sub-Zero Products, LLC
12011 Mosteller Road
Cincinnati, Ohio 45241-1528

EC Representative:

CEpartner4U B.V.
Esdoornlaan 13
3951 DB Maarn
The Netherlands

Warehouse:
7100 Dixie Highway
Fairfield, Ohio 45014

Hereby declares that the products listed below fall within Class IIb and meet the provisions of the Medical Device Directive of the European Union, 93/42/EEC, as last amended under Directive 2007/42/EC. An examination of the Quality Management System has been carried out according to the conformity assessment procedure for CE-Marking in Annex II of the directive by Notified Body DEKRA Certification B.V., Notified Body EC No. 0344. The CSZ Quality Management System complies with ISO13485:2003.

Hereby declares that the products listed below are compliant to RoHS Directive 2011/65/EU of the European Parliament and the Council from 08/06/2011 on restriction of the use of certain hazardous substances in electrical and electronic equipment (EEE).

Product name	Description	Model number	CSZ Part #	First date of CE-marking
WarmAir 135	Convective Warming Device	135	86187	1999-09
WarmAir 135	Convective Warming Device with British Leading Cord	135	86188	2012-08

7/24/2018
Jamie Allen (Date)
Director of Engineering

7/23/18
Christina M. Miracle (Date)
Manager of Regulatory Compliance

Applied standards in full or in part:

Standard No.	Title
ISO 13485:2003	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2012	Medical Devices- Application of Risk Management to Medical Devices
IEC 60601-1:2005 /A1:2012	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2007	Medical electrical equipment- Part 1-2: General requirements for safety- Collateral standard: Electromagnetic compatibility requirements and tests
IEC 60601-1-6:2010	Medical Electrical Equipment – General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 80601-2-35:2009	Medical electrical equipment – Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads or mattresses and intended for heating in medical use
EN 1041:2008	Information supplied by the manufacturer of medical devices

References:

CE-Certificate Number: 66692CE01

CSZ Tech File Number: CETF- 135

DoC Release Date: 7/24/18

Revision History:

Rev. No.	Revision Description
Orig.	Initial declaration. Previously Form #0347.15.
1	Updated DoC form revised template from 0622.5 to 0622.6. Added First Date of CE Marking column and dates. Added IEC 60601-1:2005,IEC 80601-2-35 and BS EN1041 standards to the Applied Standards. Updated IEC 60601-1-6:2007 to IEC 60601-1-6:2010. Updated IEC IEC 60601-1-2:2004 to IEC 60601-1-2:2007. Removed the Universal Stand (#91505) from the CETF. Updated ISO 14971:2007 to ISO 14971:2012.
2	Updated reference to BS EN ISO 14971:2012 by adding the BS EN. Removed reference to MEDDEV 2.7.1:2009 Guidelines on Medical Devices – Clinical Evaluation. Updated reference from BS EN 980:2008 to ISO 15223-1:2012. Updated reference to BS EN 1041:2008 by adding AM1:2013. Added IEC 60601-1-2:2004. Updated DoC template from 0622.6 to 0622.7 which added the RoHS compliance statement.
3	Added 86188 WarmAir with british leading cord to listed products table. Updated DoC template form 0622.7 to 0622.9.
4	Updated DoC template form 0622.9 to 0622.10. Removed IEC and BS from standards.
5	Updated DoC to new template, updated standards to reference EU's harmonized standards, removed irrelevant and superseded/withdrawn standards.

A GENTHERM COMPANY	Document No.: DC-016	Rev. 8

DECLARATION OF CONFORMITY

Manufacturer:

Cincinnati Sub-Zero Products, LLC
12011 Mosteller Road
Cincinnati, Ohio 45241-1528

EC Representative:

CEpartner4U B.V.
Esdoornlaan 13
3951 DB Maarn
The Netherlands

Warehouse:
7100 Dixie Highway
Fairfield, Ohio 45014

Hereby declares that the products listed below fall within Class IIb and meet the provisions of the Medical Device Directive of the European Union, 93/42/EEC, as last amended under Directive 2007/42/EC. An examination of the Quality Management System has been carried out according to the conformity assessment procedure for CE-Marking in Annex II of the directive by Notified Body DEKRA Certification B.V., Notified Body EC No. 0344. The CSZ Quality Management System complies with ISO13485:2003.

Hereby declares that the products listed below are compliant to RoHS Directive 2011/65/EU of the European Parliament and the Council from 08/06/2011 on restriction of the use of certain hazardous substances in electrical and electronic equipment (EEE).

Product name	Description	Model number	CSZ Part #	First date of CE-marking
230V Blanketrol III	Hyper/Hypothermia System	233	86207	2006-06
230V Blanketrol III (233BSI-230V)	Hyper/Hypothermia System - British Power Cord	233	86203	2013-09
230V Blanketrol III (233EL-230V)	Hyper/Hypothermia System - English Labeling	233	86204	2013-09
9' Reusable Hose	9' Reusable Connecting Hose	286	91824	1998-01
27' Reusable Hose Extension	Hose extension Reusable 287-27 27'	287-27	91831	2015-11
18' Reusable Hose	18' Reusable Connecting Hose	286-18	91840	1998-01
27' Reusable Hose	27' Reusable Connecting Hose	286-27	91841	1998-01
BIII Data Export Software	BIII USB Software	USB-127	86127	2012-07
Tri-Matic	Temp., Flow and Resistance Tester	TFRW	86171	1998-01
Hose Assembly TM-6	Hose Assembly CSZ/Trimatic (TM-6)	TM6	91802	2015-11

7/24/2018
Jamie Allen (Date)
Director of Engineering

1/23/18
Christina M. Miracle (Date)
Manager of Regulatory Compliance

Applied standards in full or in part:

Standard No.	Title
ISO 13485:2003	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2012	Medical Devices- Application of Risk Management to Medical Devices
IEC 60601-1:2005: A1:2012	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
EN 60601-1-2-:2007	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests
IEC 60601-1-6:2010	Medical Electrical Equipment – General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 80601-2:35:2009	Medical electrical equipment – Part 2-35: Particular requirements for the basic safety and esssential performance ofheating devices using blankets, pads or mattresses and intended for heating in medical use
EN 1041:2008	Information supplied by the manufacturer of medical devices

References:

CE-Certificate Number: 66692CE02

CSZ Tech File Number: CETF- 233

DoC Release Date: 7/24/18

Revision History:

Rev. No.	Revision Description
Orig.	Initial declaration
1	Updated to comply with IEC 60601-1: 2005, IEC 80601-2-35: 2009
2	Updated to new DoC template form #0622.4. Added Part No. 86265.
3	Updated DoC from revised template from 0622.4 to 0622.6. Added First Date of CE Marking column and dates. Added Tri-Matic Tester to the product list. Updated IEC 60601-1-6:2007 to IEC 60601-1-6:2010, ISTA 1C: 2001 to ISTA 1D:2001and ISO14971:2007 to ISO14971:2012 in the Applied Standards list.
4	Updated to add 230V British Power Cord Blanketrol III, Model 233 (233BSI-230V).
5	Updated reference to BS EN ISO 14971:2012 by adding the BS EN. Removed reference to MEDDEV 2.7.1:2009 Guidelines on Medical Devices – Clinical Evaluation. Updated reference from BS EN 980:2008 to ISO 15223-1:2012. Updated reference to BS EN 1041:2008 by adding AM1:2013. Updated DoC template from 0622.6 to 0622.7 which added the RoHS compliance statement. Removed TriMatic from DoC (P/N 86171). Added Blanketrol III 233EL-230V to DoC (P/N 86204).
6	Added Tri-Matic (P/N: 86171) to the DoC.
7	Updated to current template. Added 27' Reusable Hose Extension (P/N 91831) and Hose Assembly TM-6 (P/N 91802) to product list. Updated standards list to harmonized European standards where applicable.
8	Updated DoC to new template, updated standards to reference EU's harmonized standards, removed irrelevant and superseded/withdrawn standards.