

Manufacturer	Declaration of Conformity	Document ref.: TF/ 1
Cincinnati Sub-Zero Products Inc.	Date: June 17, 2011	Page: 1 of 6



DECLARATION OF CONFORMITY

1) Manufacturer: Cincinnati Sub-Zero Products, Inc.

Address: 12011 Mosteller Road, CINCINNATI, OHIO 45241-1528

and

2) European Authorized Representative: CEpartner4U BV,

Address: **Esdorndlaan 13, 3951DB Maarn, The Netherlands;**

(On product labels printed as:

CEpartner4U , Esdorndlaan 13, 3951DB Maarn, The Netherlands Tel.: +31 (0)6 516 536 26;

or as: CEpartner4U, 3951DB; 13. NL tel: +31 (0)6 – 516.536.26)

3) Product(s): (See appendix)

4) The product(s) described in Appendix I comply with:

<u>Document No.</u>	<u>Title</u>	<u>Edition / Date of issue</u>
93/42/EEC	Medical Device Directive	1993-06-14
2007/47/EC	Amendments to the MDD 93/42/EEC	2007-09-05
ISO13485:2003	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes	2003-07-15
ISO 9001:2008	Quality Management Systems - Requirements	2008-11-15 (4th ED)

5) Additional information (conformity procedure, Notified Body, CE certificate, etc.):

Conformity assessment procedure for CE marking: Medical Device Directive, Annex II

Notified Body (name and NB-nr.): KEMA Registered Quality, B.V., Nr. 0344

CE-certificate, nr: 66692CE01, 66692CE02, 66692CE03, 66692CE04.

6) All products contained within this Declaration of Conformity fall within Class II b, and meet the provisions of the applicable Council directive 93/42/EEC of 14 June 1993.

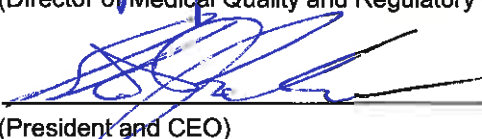
Issuance Date: 6.17.2011

(Place & date of issue in USA)

Cincinnati, OH 45241-1528



 (Director of Medical Quality and Regulatory Compliance)



 (President and CEO)

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Appendix I

List of devices:

The following devices are listed under CE Certificate #: 66692CE01

Device name	Type/model/ref number	Voltage	CSZ Part #	First date of CE-marking
WarmAir®	135	230V	86187	1999-09
Universal Stand	UNV-LPS	N/A	91505	2008-03

The following devices are listed under CE Certificate #: 66692CE02

Device name	Type/model/ref number	Voltage	CSZ Part #	First date of CE-marking
Blanketrol® II	222R	230V	86206	1998-01
Blanketrol® II	222R	240V	86109	1998-01
Blanketrol® II Low Flow Alarm	213	N/A	91031	1998-01
Blanketrol® III	233	230V	86207	2006-06
CoolBlue™ Console, INNERCOOL therapies®	25-01	230V	86001	2008-03
Norm-O-Temp®	111W	230V	86158	1998-01
Norm-O-Temp®	111W	240V	86161	1998-01
Norm-O-Temp® Stand with IV Pole	118	N/A	52301	1998-01
Norm-O-Temp® Low Profile Stand	119	N/A	52302	1998-01
Hemotherm®	400MR	230V	86012	1998-01
Hemotherm®	400MR	240V	86015	1998-01
Hemotherm®	400CE	230V	86023	2009-02
Hemotherm® Remote	414	N/A	93803	1998-01
Hemotherm® Remote	414CE	N/A	93816	2009-11
Hemotherm® Remote Control Port Cable	415	N/A	39807	1998-01
Hemotherm® Universal Mounting Clamp	UMC-1	N/A	91811	1998-01

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Device name	Type/model/ref number	Voltage	CSZ Part #	First date of CE-marking
Hemotherm® Flow Tester	400MR-FT	N/A	93002	1998-01
Hemotherm® Flow Indicator with Shut-off Valve Assembly	420	N/A	93808	1998-01
Micro-Temp® II	747	230/240V	88220	2003-04
Micro-Temp® LT	749	230/240V	88221	2007-01
Micro-Temp® II / Micro-Temp® LT Adapter Plate for Universal Stand	MT-081	N/A	71081	2008-03
Electri-Cool® II	767	230/240V	86194	2004-01
Electri-Cool® II Adapter Plate for Universal Stand	EC-080	N/A	71080	2008-03
Tri-Matic	TFRW	N/A	86171	1998-01
Connection Hose	186	N/A	89186	2011-02
Connection Hose	286	N/A	91824	1998-01
Connection Hose	286-18	N/A	91840	1998-01
Connection Hose	286-27	N/A	91841	1998-01
Connection Hose	287	N/A	91825	1998-01
Connection Hose	287-18	N/A	91826	1998-01
Connection Hose	287-27	N/A	91831	1998-01
Connection Hose, INNERCOOL therapies®	26-01	N/A	91844	2008-03

The following devices are listed under CE Certificate #: 66692CE03

Device name	Type/model/ref number	Voltage	CSZ Part #	First date of CE-marking
Warming Tube™	145	N/A	82145	1998-01
FilteredFlo® Adult Blanket	243	N/A	82243	2003-08
FilteredFlo® Pediatric Blanket	244	N/A	82244	2003-08
FilteredFlo® Lower Body Blanket	442	N/A	82442	2003-08
FilteredFlo® Upper Body Blanket	443	N/A	82443	2003-08

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Device name	Type/model/ref number	Voltage	CSZ Part #	First date of CE-marking
FilteredFlo [®] Torso Blanket	344	N/A	82344	2003-08
FilteredFlo [®] Cardiac Blanket	542	N/A	82542	2004-05
FilteredFlo [®] Neonate/Pediatric Blanket	246	N/A	82246	2005-11

The following devices are listed under CE Certificate #: 66692CE04

Device name	Type/model/ref number	Voltage	CSZ Part #	First date of CE-marking
Maxi-Therm [®]	276	N/A	50230	1998-01
Maxi-Therm [®]	273	N/A	50232	1998-01
Maxi-Therm [®]	274	N/A	50231	1998-01
Maxi-Therm [®] Lite	870	N/A	82170	1998-01
Maxi-Therm [®] Lite	871	N/A	82171	1998-01
Maxi-Therm [®] Lite	872	N/A	82172	1998-01
Maxi-Therm [®] Lite	873	N/A	82173	1998-01
Maxi-Therm [®] Lite	874	N/A	82174	1998-01
Maxi-Therm [®] Lite	876	N/A	82176	1998-01
PlastiPad [®]	193	N/A	82193	1998-01
PlastiPad [®]	194	N/A	82194	1998-01
PlastiPad [®]	195N	N/A	50103	1998-01
PlastiPad [®]	196	N/A	82196	1998-01
PlastiPad [®]	196M	N/A	82190	2004-02
Maxi-Therm [®] Lite Patient Vest	800	N/A	82800	2004-07
Head Wrap	600	N/A	82600	2004-09
Temp-Pad [®]	305NS	N/A	50721	2005-12
Temp-Pad [®]	510NS	N/A	50733	2005-12
Temp-Pad [®]	814NS	N/A	50734	2005-12
Temp-Pad [®]	1112NS	N/A	50735	2005-12
Temp-Pad [®]	305-USS	N/A	50621	2007-10
Temp-Pad [®]	510-US	N/A	50625	2007-10

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Device name	Type/model/ref number	Voltage	CSZ Part #	First date of CE-marking
Temp-Pad®	510-USS	N/A	50633	2007-10
Temp-Pad®	814-US	N/A	50627	2007-10
Temp-Pad®	1112-US	N/A	50628	2007-10
Temp-Pad®	318-US	N/A	50624	2007-10
Temp-Pad®	1215-US	N/A	50629	2007-10
Temp-Pad®	1112-USS	N/A	50635	2007-10
Temp-Pad®	814-USS	N/A	50634	2007-10
COOLTEMP® PAD	CT-99NS	N/A	50737	2005-12
COOLTEMP® PAD	CT-99	N/A	50137	2007-10
ImmobilICE™ SUPPORT – Universal Back	814 IMB	N/A	50651	2005-12
ImmobilICE™ SUPPORT – Universal Hip	814 IMH	N/A	50652	2005-12
Gelli-Roll™	193P	N/A	82197	2007-05
Gelli-Roll™	194P	N/A	82198	2007-05
Gelli-Roll™	195P	N/A	82199	2007-05
Kool Kit™	900	N/A	82900	2007-08
Kool Kit™ Head Wrap Kit	910	N/A	82910	2008-01
Kool Kit™ Patient Vest Kit	920	N/A	82920	2008-01
Kool Kit™ Neonate	950	N/A	82950	2011-06
Maxi-Therm® Lite	875	N/A	82103	2007-08
Right Thigh Pad, INNERCOOL therapies®	N/A	N/A	82132	2008-03
Left Thigh Pad, INNERCOOL therapies®	N/A	N/A	82133	2008-03
Small/Medium Size Torso Pad, INNERCOOL therapies®	N/A	N/A	82130	2008-03
Large/X-Large Size Torso Pad, INNERCOOL therapies®	N/A	N/A	82131	2008-03
Small/Medium CoolBlue™ Surface Pad Kit, INNERCOOL therapies®	14-01	N/A	82501	2008-03

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Device name	Type/model/ref number	Voltage	CSZ Part #	First date of CE-marking
Large/X-Large CoolBlue™ Surface Pad Kit, INNERCOOL therapies®	14-02	N/A	82502	2008-03
CoolBlue™ Replacement Thigh Pad Kit, INNERCOOL therapies®	14-03	N/A	82503	2008-03