Anexa nr. 1
La Procedurile administrative pentru notificarea dispozitivelor medicale care deţin marcajul CE

Către Agenţia Medicamentului
şi Dispozitivelor Medicale

NOTIFICARE
pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale
nr. 1 din 14.07.2023

Solicitantul SRL Biosistem mld, cu sediul str. Albișoara 16/1 of.7, or. Chișinău
(adresa)
Tel./Fax: .+373-22-808517, +373-22-808719, fax +373-22-808519, e-mail biosistem.mld@gmail.com; info@biosistem-mld.com, solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii şi tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a:

1. Water Hyper/Hypothermia Blanket

Se anexează următoarele acte:
Declaraţie pe proprie răspundere
CE certificate
Declaratie de conformitate
Scrisoare de imputernicire

Data 14.07.2023 Semnătura _____

Tabelul de recepționare a notificării
(se completează de către Agenție în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	
Semnătura persoanei responsabile	

Digitally signed by Poiata Vitalie
Date: 2023.07.14 12:36:34 EEST
Reason: MoldSign Signature
Location: Moldova

Anexa nr. 2
La Procedurile administrative pentru notificarea
dispozitivelor medicale care dețin marcajul CE

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAŢIE PE PROPRIE RĂSPUNDERE

Solicitant: SRL Biosistem mld, cu sediul str. Albișoara 16/1 of.7, or. Chișinău, declar pe proprie răspundere, cunoscând prevederile art. **352[1]**, Codul Penal al Republicii Moldova cu privire la falsul în declaraţii, că documentele și datele furnizate pentru notificarea dispozitivului medical:

1. Water Hyper/Hypothermia Blanket

Sunt autentice și corespund realității.

Administrator: Poiata Vitalie *Semnătura* _____

Data 14.07.2023

GENTHERM

Technology to the next degree™

To: Whomever it may concern

Biosistem-mld SRL
Albisoara 16/1 ap.7
Chisinau, R. Moldova

July 7th 2023

MANUFACTURERS AUTHORIZATION

We, Gentherm Medical LLC manufacturer of medical products with principal place of business at 12011 Mosteller Road, Cincinnati, OH 45241, USA hereby confirm that **Biosistem mld SRL** with business office at Albisoara 16/1 ap.7, Chisinau, Republic of Moldova, is authorized to register our products in Moldova.

BIOSISTEM mld agrees to comply with relevant medical device regulations in Moldova.

This authorization is valid for 1y from the date of issuance and automatically renewable if no termination letter issued.

Yours Very Truly,

Felix Stihler
Site Managing Director
& Head, Business Development EMEA Gentherm Medical

DECLARATION OF CONFORMITY

Manufacturer:

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

EC Representative:

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

CSZ Medical 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
Gelli-Roll	Infant	193P	82197	2007-05
Gelli-Roll	Pediatric	194P	82198	2007-05
Gelli-Roll	Adult	195P	82199	2007-05

Steven J. Berke
President

Christina Miracle
Manager of Regulatory Compliance

Applied standards in full or in part:

Standard No.	Title
ISO 13485:2003	Quality Management Systems – Requirements for Regulatory Purposes
ISO 10993-1:2009	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2009)
EN ISO 14971:2012	Medical Devices – Application fo Risk Management to Medical Devices
EN 60601-1-6:2010	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability.
EN 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 Matresses and Intended for Heating in Medical Use
ISTA 1C:2001	International Shipping Standards – Non-Simulating Integrity Performance Test Procedure
EN 980:2008	Symbols for use in the labelling of medical devices
EN 1041:2008	Information Supplied by the Manufacturer of Medical Devices

References:

CE-Certificate Number: 66692CE04

CSZ Tech File Number: CETF-193P

Christina Miracle
Manager of Regulatory Compliance

Revision History:

Rev. No.	Revision Description
Orig.	Initial declaration
1	Updated DoC form revised template from 0622.5 to 0622.6, Added First Date of CE Marking column and dates., Simplified the ISO 13485:2003 date, 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, Guidleines 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 0.622.6 to 0.622.7 which added the RoHS compliance statement, Updated to include Manager of Regulatory Compliance
3	Updated Manager of Regulatory compliance. Removed BS and IEC from standards.

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

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: **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

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

DECLARATION OF CONFORMITY

Manufacturer:

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

EC Representative:

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

CSZ Medical 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
Plastipad Blanket	Reusable, Hyper/Hypothermia Blanket Infant (12" x 18")	193CPC	82192	1998-01
PlastiPad Blanket	Reusable Hyper/Hypothermia Blanket Adult (24" x 60")	196CPC	82184	2014-12
PlastiPad Blanket	Reusable Hyper/Hypothermia Blanket Pediatric (22" x 30")	194CPC	50111	2014-12
Plastipad Blanket	Reusable, Hyper/Hypothermia Blanket Adult (20" x 60")	195N	50103	1998-01
PlastiPad Blanket	Reusable, Hyper/Hypothermia Blanket Infant (12" x 18")	193	82193	1998-01
PlastiPad Blanket	Reusable Hyper/Hypothermia Blanket Pediatric (22" x 30")	194	82194	1998-01
PlastiPad Blanket	Reusable Hyper/Hypothermia Blanket Adult (24" x 60")	196	82196	1998-01

Steven J. Berke
President

Christina Miracle
Manager of Regulatory Compliance

Applied standards in full or in part:

Standard No.	Title
ISO 13485:2003	Quality Management Systems - Requirements for Regulatory Purposes
ISO 10993-1:2009	Biological Evaluation of Medical Devices – Part1: Evaluation and Testing Within a Risk Management Process
EN ISO 14971:2012	Medical Devices-Application of Risk Management to Medical Devices
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 Matresses and Intended for Heating in Medical Use
ISTA 1C:2014	International Shipping Standards – Non-Simulating Integrity Performance Test Procedure
EN 980:2008	Symbols for use in the labelling of medical devices
EN 1041:2008	Information Supplied by the Manufacturer of Medical Devices

References:

CE-Certificate Number: 66692CE04

CSZ Tech File Number: CETF-193

Christina Miracle
Manager of Regulatory Compliance

Revision History:

Rev. No.	Revision Description
Orig.	Initial declaration
1	Updated DoC form revised template from 0622.5 to 0622.6. Added First Date of CE Marking column and dates. Added 9' Reusable Extension Hose (186) to product list. Deleted part number # 50111 (194CPC). Updated standard ISO 14971:2007 to ISO 14971:2012. Simplified ISO 13485:2003 date.
2	Updated DoC form revised template from 0622.6 to 0622.7 which added the RoHS compliance statement; 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 to remove part numbers that have been determined non-RoHS compliant, Updated to include Manager of Regulatory Compliance
3	Updated DoC to include part number #50111 (Cat#194CPC) and #82184 (Cat#196CPC), Updated to include Director of Quality & Regulatory Compliance
4	Removed IEC and BS from standards. Updated the Manager of Regulatory Compliance.
5	Added Cat 193, 194, and 196.