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EC CERTIFICATION

FULL QUALITY ASSURANCE SYSTEM

Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the Swedish national legislation LVFS 2003:11 to which the undersigned is subjected, transposing Annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive, and the result entitles the organization to use the CE 0413 marking on those products listed below.

Organization:

KanMed AB

Main Site: Gårdsfogdevägen 18B, Bromma, 168 67 Sweden

Product Category:

- Patient Warming Systems

For further identification of the products covered, see the MDD product list/product schedule.

Certificate Number:
41313430-04

Initial Certification Date:
19 June 2000

Certificate Valid from:
20 June 2020

Certificate Expiry Date:
26 May 2024

SWEDAC ACKREDITERING
Accred. no. 1003
Certification of Management Systems
ISO/IEC 17021-1

Peter Nermander
Certification Authority MDD
Intertek Semko AB, Kista, Sweden

18 June 2020
Signed Date

Intertek Semko AB
Box 1103, SE-164 22 Kista, Sweden
Telephone +46 8 750 00 00
medtechsweden@intertek.com

The certification is subject to the organization maintaining their system in compliance with the regulations stated in this certificate, allowing regular assessments and following the contracted requirements of the Notified Body.

Intertek Semko AB is a Notified Body according to Directive 93/42/EEC on medical devices, with identification number 0413.

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MDD – Product List

Products included in the Certificate No: 41313430-04
Issued to: **KanMed AB**
Gårdsfogdev 18B
SE-168 67 Bromma
Sweden

Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)	Date added
Patient Warming Systems					
	Patient Warming				
	Heating Pads				
	OP3-063, 63 cm	IIb	-		*
	OP3-104, 104 cm	IIb	-		*
	OP3-150, 150 cm	IIb	-		*
	WarmCloud				
	9000	IIb	No	37328	Feb 03, 2017
	Infant Warming				
	Baby Warming System				
	BW3-020	IIb	-		March 15, 2011
	Heating Pads				
	BW-50-002	IIb	-		*
	BW3-003	IIb	-		March 15, 2011

* Product added before June 19, 2010.

Date of Issue: 18 June 2020
Valid from: 20 June 2020

Intertek Semko AB
Notified Body MDD

Peter Nermander
Certification Authority MDD

This product list is only valid together with the referenced, valid EC certificate.

The GMDN codes are assigned by the manufacturer and are only provided for convenience.

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MDD – Decision Report

Certificate No: 41313430-04
Date: 18 June 2020
Handled by: Caroline Åman
E-mail: medtechsweden@intertek.com

KanMed AB
Attn: Annika Engstrand
Gårdsfogdev 18B
SE-168 67 Bromma
Sweden

Purpose	Assessment to issue a new certificate due to five year extension according to the national legislation for medical devices LVFS 2003:11 (Medical Device Directive 93/42/EEC), Annex II.
Activity	Certification audit was performed 9 January 2020 in Bromma by Anders Beck. The technical file was reviewed 17 June 2020 by Stephen Ward at Intertek's office.
Scope of assessment	Patient Warming Systems, Class IIb
Result	No non conformities were noted during the audit. From the rerview of the technical file, no open non-conformities remains. Two minor non-conformities are pending follow-up of implemented correction where the plan has been accepted.
Certificate Valid from	20 June 2020
Conclusions/Decisions	Referring to the above a Certificate of Conformance with the national legislation for medical devices LVFS 2003:11 (Medical Device Directive 93/42/EEC), Annex II will be issued. The Certificate is valid for products specified in the "MDD – Product List".
Follow-up assessments	Follow-up assessments are going to be performed once a year.
Appeals	Any appeal against this decision will be processed by an appeals panel as Intertek. The appeal shall be submitted to Intertek Semko AB, PO-Box 1103, SE-164 22 Kista, Sweden.
Others	Any complaints, from customers and others, and corrective actions concerning your certified quality system shall be documented and retained. Upon request Intertek Semko has the right to review this documentation.

Intertek Semko AB
Notified Body MDD

Peter Nermander
Certification Authority MDD