

# EC Certificate

**FULL QUALITY ASSURANCE SYSTEM**

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

**Certificate Number**  
41313430-02

**Initial Certification Date**  
June 19, 2000

**Certificate Valid from**  
September 23, 2016

**Certificate Expiry Date**  
June 19, 2020

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.

*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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**Organization:**

**KanMed AB**

Gårdsfogdevägen 18B, SE – 168 67 Bromma, Sweden

**Product Category:**

Patient Warming Systems

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



Akkred. nr 1003  
ISO/IEC 17021

September 23, 2016

Signed date

Mats Premfors, Certification Authority MDD  
Intertek Semko AB, Kista, Sweden

Products included in the Certificate No: 41313430-02  
 Issued to: **KanMed AB**  
 Gårdsfogdev 18B  
 SE-168 67 Bromma  
 Sweden

Product category	Type/Model designation	Class	Sterile	GMDN code <small>(not mandatory)</small>	Date added
<b>Patient Warming Products</b>					
<i>Heating Pads:</i>					
	OP-200-002	IIb	-		*
	OP-200-012	IIb	-		*
	OP-200-221	IIb	-		*
<b>Operatherm control unit</b>					
<i>Heating Pads</i>					
	OP3-050, 50 cm	IIb	-		*
	OP3-063, 63 cm	IIb	-		*
	OP3-104, 104 cm	IIb	-		*
	OP3-150, 150 cm	IIb	-		*
<b>Baby Warming System</b>					
	BW-50-020	IIb	-		*
	BW3-020	IIb	-		March 15, 2011
<i>Heating Pads</i>					
	BW-50-002	IIb	-		*
	BW3-003	IIb	-		March 15, 2011
<b>WarmCloud</b>					
	9000	IIb	No	37328	Feb 03, 2017

\* Product added before June 19, 2010.

Date of Issue: October 31, 2018

**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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Product List for Certificate No: 41313430-02  
 Date: October 31, 2018  
 Page 1 of 1