

EC Certificate

FULL QUALITY ASSURANCE SYSTEM

Directive 93/42/EEC on Medical Devices, Annex II (3)

Certificate Number
41313430

Initial Certification Date
June 19, 2000

Certificate Valid from
June 19, 2010

Certificate Expiry Date
June 19, 2015

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.

*Intertek Semko AB
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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 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

Gårdsfogdevägen 18B, SE – 168 66 Bromma, Sweden


Product Category:

- Patient Warming Systems

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

June 3, 2010

Signed date


Marie Olsson, Certification Manager MDD
Intertek Semko AB, Kista, Sweden

Products included in the Certificate No: 41313430
 Issued to: **KanMed AB**
 Gårdsfogdev 18B
 SE-168 66 Bromma
 Sweden

Product category	Type/Model designation	Class	Sterile	GMDN code <small>(not mandatory)</small>	Date added
Patient Warming Products:					
Heating Pads	OP-200-002	IIb	-		*
	OP-200-012	IIb	-		*
	OP-200-221	IIb	-		*
Warm Cloud System	OT-600-001	IIb	-		*
Operatherm control unit					
Heating Pads	OP3-022	IIb	-		*
	OP3-050, 50 cm	IIb	-		*
	OP3-063, 63 cm	IIb	-		*
	OP3-104, 104 cm	IIb	-		*
	OP3-150, 150 cm	IIb	-		*
Baby Warming Products:					
Baby Warming System	BW-50-020	IIb	-		*
	BW3-020				March 15, 2011
Heating Pads	BW-50-002	IIb	-		*
	BW3-003	IIb			March 15, 2011

* Product added before June 19, 2010.

Date of Issue: March 15, 2011

Intertek Semko AB
 Notified Body MDD



Marie Olsson
 Certification Manager 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
 Date: March 15, 2011
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