EC CERTIFICATION

EU Quality Management System Certificate

Regulation (EU) 2017/745 for Medical Devices, Annex IX Chapters I & III

We hereby declare that a conformity assessment based on a quality management system and technical documentation has been carried out following the requirements of Regulation (EU) 2017/745 for Medical Devices.

We certify that the documentation conforms to the relevant provisions of the aforementioned regulation, and the result entitles the organization to use the CE 2862 marking on the products listed below.

Kanmed AB

Hammarbacken 6A, Sollentuna, 191 49 , Sweden

Manufacturer SRN: SE-MF-000001839

Scope:

Patient warming device

Certificate Number:
28620221903

Revision:
00

Initial Certification Date:
26 August 2025

Certificate Decision Date:
26 August 2025

Certificate Issue Date:
26 August 2025

Certificate Expiry Date:
9 June 2030

Brian Mather
Certification Authority, MDR
Intertek Medical Notified Body AB,
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Intertek Medical Notified Body AB is a Notified Body in accordance with the requirements set out in EU Regulation 2017/745 on medical devices, with the identification number 2862.

In the issuance of this certificate, Intertek assumes no liability to any party other than to the Client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organization maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at certificate.validation@intertek.com or by scanning the code to the right with a smartphone.

The certificate remains the property of Intertek, to whom it must be returned upon request.

PRODUCT LIST FOR CERTIFICATE

See attached product list

EXAMINATION AND TESTS PERFORMED

Technical Assessment Report Reference	**TD00221-001 BabyWarmer BW3**
Audit Report Reference	**Stage 1 audit ACTY-2022-556488**
	Stage 2 audit ACTY-2022-556489
	Special Surveillance audit ACTY-2020-448961
Change Notice Reference	

CONDITIONS FOR OR LIMITATIONS TO VALIDITY OF CERTIFICATE

None

CERTIFICATE HISTORY

PRECEDING CERTIFICATE NUMBER	DATE OF ISSUE	IDENTIFICATION OF CHANGES
28620221903	26 August 2025	Initial Certificate

Certificate Number:
28620221903

Revision:
00

Initial Certification Date:
26 August 2025

Certificate Decision Date:
26 August 2025

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PRODUCT LIST FOR CERTIFICATE

Issued to: Kanmed AB

Certificate number: 28620221903

Certificate valid from: 2025-08-26

Product List Issue Date:
26 August 2025

Product	Classification and EMDN	Intended use[1]	Date Added
Patient warming device			
Basic UDI-DI: 73500451230511313XH			
BW3-020 - BabyWarmer BW3	Class IIb Z12040208	The intended use of the KANMED BabyWarmer BW3 is to keep new born and premature babies normothermic. KANMED BabyWarmer BW3 is designed for hospital use only. It must be used according to the instructions in this manual and according to established clinical routines and by qualified personnel.	2025-08-26
Basic UDI-DI: 73500451230511318XT			
BW3-003 - Heating pad BW3	Class IIb Z12040208	The intended use of the KANMED Heating pad BW3 is to keep new born and premature babies normothermic. KANMED Heating pad BW3 is designed for hospital use only. It must be used according to the instructions in this manual and according to established clinical routines and by qualified personnel.	2025-08-26
Basic UDI-DI: 73500451251311313YE			
9000 - WarmCloud	Class IIb Z12040208	The Kanmed WarmCloud 2 is a pressure relieving warm air mattress intended to be used pre, intra and post operatively in a hospital environment by qualified hospital staff. The system is intended to reduce the risk of hypothermia and pressure sores. The system can be used for patients weighing up to 135kg. The system must not be used when blood vessels are blocked off; this as warming then could cause serious injury to patient.	2025-08-26

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[1]The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.