

DECLARATION OF CONFORMITY

According to EU 2017/745 Medical Device Regulation (MDR)

Type of equipment: Baby Warmer Accessories

Brand name or trademark: Kanmed Baby Warmer Foam Mattress
(Foam Mattress)

Type designation / Model No: BW3-203

Intended use: The Kanmed Foam Mattress is used together with the Kanmed Baby Warmer and it is therefore qualified as accessory to a medical device.

The intended use of the Kanmed Baby Warmer is to keep newborn and premature babies normothermic. Kanmed BabyWarmer BW3 is designed for hospital use only. It must be used according to the instructions in the manual and according to established clinical routines and by qualified personnel.

Classification: Class I

Manufacturer: Kanmed AB
Hammarbacken 6A
SE-191 49 Sollentuna
Sweden

SRN: SE-MF-000001839


Basic-UDI: 73500151230511513XT

Conformity assessment route: Declaration of conformity according to Article 52, paragraph 7

We hereby declare that the above-mentioned device complies with the EU 2017/745 Medical Device Regulation.

Place: Sollentuna, Sweden

Date: 2023-12-05

Signature: 

Name: Marcus Nanayakkara

Position: CEO