

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 Water Mattress
(Water Mattress 4.5 l, Water Mattress Twin, Water Mattress for BabyBed)

Type designation / Model No: BW-50-003, BW-50-015, BW-50-10

Intended use: The Kanmed Water 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: 73500151230511413XN

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

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

Place: Sollentuna, Sweden

Date: 2024-01-26

Signature:

Name:

Marcus Nanayakkara

Position:

CEO