

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

Type of equipment: Baby Bed Accessories

Brand name or trademark: Kanmed BabyBed Foam Mattresses
(Foam Mattress, Foam Mattress twin)

Type designation / Model No: BB-20, BB155, BB450

Intended use: The Kanmed BabyBed Foam Mattresses are used together with the Kanmed BabyBed and they are therefore qualified as accessories to a medical device.

The intended use of the Kanmed BabyBed is to provide an ideal ergonomic and safe Bed for premature and new born babies in a hospital environment. It is also intended to be used with the Kanmed BabyWarmer systems BW3 or BW-50.

It is intended to be used by hospital personnel or the baby's caretaker according to the instructions given in the manual and according to your established clinical routines. Only persons that have been instructed in the use of the Kanmed BabyBed shall be allowed to use the product.

Classification: Class I

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

SRN: SE-MF-000001839


Basic-UDI: 73500451230301413WH

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: Bromma, Sweden

Date: 2023-12-04

Signature: 

Name: Marcus Nanayakkara

Position: CEO