

DECLARATION OF CONFORMITY

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

Type of equipment: Baby Bed Accessories

Brand name or trademark: Kanmed BabyBed Tents
(Tent BabyBed, Tent BabyBed twin)

Type designation / Model No: BB-21, BB-22, BB160, BB161, BB162, BB460

Intended use: The Kanmed BabyBed Tents 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
Gårdsfogdevägen 18B
SE-168 67 Bromma
Sweden

SRN: SE-MF-000001839


Basic-UDI: 73500451230301513WN

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: 2022-09-08

Signature: 

Name: Marcus Nanayakkara

Position: CEO

KANMED^o
Org.nr 556188-1060
Gårdsfogdevägen 18B
168 67 Bromma
Tel. +46 8-564 80 630
Fax +46 8-564 80 639