

DECLARATION OF CONFORMITY

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

Type of equipment:

Baby Bed

Brand name or trademark:

Kanmed BabyBed

Type designation / Model No:

BB100, BB101, BB102

BB300, BB301, BB302

BB400, BB400F, BB401, BB401F, BB402

Intended use:

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:

73500451230301313WC

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

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