

DECLARATION OF CONFORMITY

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

Type of equipment: Warm air mattress

Brand name or trademark: Kanmed WarmCloud Mattress (WarmCloud mattress short, WarmCloud mattress long)

Type designation / Model No: OT-600-211, OT-600-222

Intended use: The Kanmed WarmCloud Mattress is a pressure relieving warm air mattress intended to be used pre, intra and post operatively in a hospital environment by qualified hospital staff. The mattress shall be used with the Kanmed WarmCloud device and is intended to reduce the risk of hypothermia and pressure sores.

The system can be used for patients weighing up to 135kg.

The system must not be used when blood vessels are blocked off; this as warming then could cause serious injury to patient.

Classification: Class I

Manufacturer: Kanmed AB
Gårdsfogdevägen 18B
SE-168 67 Bromma
Sweden

SRN: SE-MF-000001839


Basic-UDI: 73500451251311413YK

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: 2021-05-21

Signature: 

Name: Marcus Nanayakkara

Position: CEO