

DECLARATION OF CONFORMITY

According to Annex II Medical Device Directive 93/42 EEC

Type of equipment: Patient Warmer for Hospital use.

Brand name or trade mark: Kanmed Operatherm

Type designation / Model Nos: Standard Heating Pad, **OP3-104**,
Short Heating Pad, **OP3-063**

Manufacturer: Kanmed AB
Gårdsfogdevägen 18 B
168 66 BROMMA
SWEDEN

Standards: IEC 60 601-1 (2005): Medical electrical equipment - General requirements for the basic safety and essential performance
IEC 80 601-2-35 (2009): Medical electrical equipment – Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads or mattresses and intended for heating in medical use.

Test reports: TR120620
TR120822

MDD: Class I Ib

We hereby declare that the above mentioned devices comply with the national legalisation of LVFS 2003:11 transposing European Medical Devices Directive 93/42/EEC and the Swedish Medical Devices Act (1993:584).

CE marking introduced 2008

Bromma

2023-03-23

Authorized person:



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