

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
Hammarbacken 6A
191 49 Sollentuna
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 IIb

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

Sollentuna

Authorized person:

2023-12-05


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CEO