Declaration Conformity of Infant Radiant Warmer
(CE Technical File_Part A)

DAVID

Declaration of Conformity

Manufacturer: Ningbo David Medical Device Co.,Ltd

Address : No.2,Keyuan Road, Shipu Science and Technology Park,Xiangshan315731
Ningbo, Zhejiang Province, PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Ningbo David Medical Device Co.,Ltd
No.2,Keyuan Road, Shipu Science and Technology Park,Xiangshan315731
Ningbo, Zhejiang Province, PEOPLE'S REPUBLIC OF CHINA

European Representative: Shanghai International Holding Corp.GmbH(Europe)
Eiffestrasse 80, 20537 Hamburg Germany

Product Category: Infant Radiant Warmer

Model: HKN-2001 Series (including HKN-2001 and HKN-2001L)
HKN-93 Series (including HKN-93, HKN-93A, HKN-93B, HKN-93C and HKN-93CS)
HKN-500 Series (including HKN-500, HKN-500A, HKN-500B and HKN-500AB)
HKN-2200 Series (including HKN-2200, HKN-2200A and HKN-2200B)
HKN-2500 Series (including HKN-2500, HKN-2500A and HKN-2500B)
HKN-9010
HKN-90

Classification:class IIb, based on MDD 93/42/EEC annex IX Rule 9

The GMDNS Code: 17433

Conformity Assessment Route: Annex **II.3** of MDD 93/42/EEC

We declare that compliance of the above medical device with the applicable requirements of Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC. All the supporting documents and files are retained under the premises of the manufacturer. We are exclusively responsible for the documents.

Notified Body: TÜV SÜD Product Sevice GmbH , Zertifizierstelle, Ridlerstrasse 65,80339 MÜnchen, Germany

Identification Number: 0123

Certificate No.: G1 032913 0043 Rev.00

Expire date of the Certificate: 2024-05-26

Confirmation Statement Certificate No.: GCQ 032913 0047 Rev.00

In relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 as regards the transitional provisions for certain medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD)

(Directive Certificates), *and*

- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service.

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met, *and*
- the **device(s)** listed above and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service.

End date of extended validity / transition period: 2028-12-31

Confirmation Letter No.: CL 032913 0049 Rev. 00

Signature: _____

Name: Mr.Dingyu Lin

Position: Person Responsible for Regulatory Compliance

Place, Date of Issue: Xiangshan, Ningbo, Zhejiang, 2024/05/27

CE 0123