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

Ningbo David Medical Device Co.,Ltd
No.35,Jinxing Road, Binhai Industrial Park, Xiangshan Economic Development Zone,315712Ningbo,Zhejiang Province, PEOPLE'S REPUBLICOF CHINA

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

Product Category: Transcutaneous Jaundice Detector
Model: BM-100A, BM-100B, BM-100C
Classification: class IIa, based on MDD 93/42/EEC annex IX Rule 10
The GMDNS Code: 16166
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
Start of CE-Marking: 2021-03-23
Place, Date of Issue: Xiangshan, Ningbo, Zhejiang, 2021/04/01

Signature:
Name: Mr.Chen Zaihong
Position: Director

CE 0123