



Declaration of Conformity

Manufacturer Guangdong Biolight Meditech Co., Ltd
Address No.2 Innovation First Road, Technical Innovation Coast, Hi-tech Zone, Zhuhai,
P.R. China
European Representative Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg Germany
Product Pulse Oximeter
GMDN Code 45607
Model Code MASTER PALM 3[®] (SN: M-017-E-000001~M-017-E-999999)

Classification: Class II b , rule 10 of Annex IX of the MDD 93/42/EEC

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

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

DIRECTIVES

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC concerning medical devices (MDD 93/42/EEC).

Standard:

All applicable harmonized Standard (published in the Official Journal of the European Communities).

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339
München, Germany

Identification number: 0123

(EC) Certificate(s): G1 15 09 49957 026

Expire date of the Certificate: 2020-03-19

Start of CE marking: Jan.18, 2018

Place, Date of Issue: Zhuhai, China, Jan 18, 2018

Signature

Name Daoguo Zhang

Position R&D Director