

EU DECLARATION OF CONFORMITY

Name and address of the manufacturer: **Shenzhen Creative Industry Co., Ltd.
Floor 5, BLD 9, Baiwangxin High-Tech Industrial Park,
Songbai Road, Xili Street, Nanshan District, 518110
Shenzhen, PEOPLE'S REPUBLIC OF CHINA**

SRN (Manufacturer) **CN-MF-000009430**

Name and address of Authorized Representative: **Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg GERMANY**

SRN (EU Authorised) **DE-AR-000000001**

We declare that the product concerned has been designed and manufactured under a quality management system according to Regulation(EU) MDR 2017/745 Article 120, Annex II of 93/42/EEC and Regulation (EU) 2023/607

Medical Device: **Fingertip Oximeter
Model: PC-60A/PRINCE-100A/PC-60B/POD-1W/POD-1/POD-2/POD-3/PC-60C/PC-60NW/PC-60N/PRINCE-100N/PC-60B1/PC-60D/PRINCE-100D/PC-60D2/PRINCE-100D2/PC-60E/PRINCE-100I**

GMDN **45607**

Risk class: **Class IIa**

Basic UDI-DI **69419006FOximeter0101ZT; 69419006FOximeter0102ZV;
69419006FOximeter010322; 69419006FOximeter010424**

Conformity assessment procedure: **93/42/EEC Annex II excluding(4)**

The EU declaration of conformity is issued under sole responsibility of the manufacturer. We hereby declare that the above mentioned products meet the provisions of the following EUROPEAN PARLIAMENT AND OF THE COUNCIL Regulation and Applicable standards. All supporting documents are retained under the premises of the manufacturer.

Regulations **MDR 2017/745 Article 120
93/42/EEC
Regulation (EU) 2023/607**

Applicable CS or Standard(s) **EN 60601-1:2006 +A2:2020
EN 60601-1-2:2014+A1:2020
EN 60601-1-11:2015+A1:2020
EN ISO 80601-2-61:2019
EN ISO 10993-1:2020
EN ISO 10993-5:2009
EN ISO 10993-10:2010
EN ISO 14971:2019+A11-2021
EN ISO 15223-1:2021**

Certificate No.: **G1 049076 0016 REV.03; CL 049076 0017 Rev.00**

Issue date: **2021-04-26**

Expiry date: **2028-12-31**

Notified Body: **TÜV SÜD Product service GmbH
Ridlerstr 65, D-80339 München, Germany**

Shenzhen, 2023/12/23
Place, date



Zhang Xiang Management Representative
Name and function

81-RA-00300 revA