EU DECLARATION OF CONFORMITY

Name and address of the manufacturer:	**Shenzhen Creative Industry Co., Ltd.** **1001, Building West, Lepu Tower, No.66 Xingke Road, Xili Community, Xili Street, Nanshan District, 518055 Shenzhen, PEOPLE'S REPUBLIC OF CHINA**
SRN (Manufucturer)	**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:	**Handheld Pulse Oximeter** **Model: PC-66B/PC-66V/Prince-100F/SP-20**
GMDN:	**45607**
Risk class:	**Class IIa**
Basic UDI-DI	**69419006HPOximeter0101HL**
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+A1: 2013+A2:2021** **EN 60601-1-2: 2015+A1:2021** **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: 2023** **EN ISO 10993-23:2021** **EN ISO 14971:2019+A11:2021** **EN ISO 15223-1:2021** **EN ISO 20417:2021** **EN ISO 14155:2020**
Certificate No.:	**G1 049076 0016 REV.03; CL 049076 0017 Rev.01**
Issue date:	**2021-04-26**
Expiry date:	**2028-12-31**
Notified Body:	**TÜV SÜD Product service GmbH** **Ridlerstr 65, D-80339 München, Germany**

Shenzhen, 2025/9/30
Place, date

Zhang Xiang Management Representative
Name and function