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:	**Lepu Medical (Europe) Coöperatief U.A.** **Abe Lenstra Boulevard 36, 8448 JB Heerenveen, Netherland**
SRN (EU Authorised)	**NL-AR-000000551**

We declare that the product concerned has been designed and manufactured under a quality management system according to Annex IX of Regulation EU 2017/745(MDR).

Medical Device:	**Handheld Pulse Oximeter** **Model: SP-20, PC-66A**
Attachment	**SpO2 probe for SP-20 and PC-66A: KS-AC01, KS-AC02, KS-AYW02, KS-AR01, KS-AR02**
Intended use/purpose:	**This Handheld Pulse Oximeter is intended for measuring and recording the pulse rate, functional oxygen saturation (SpO2), receive and display temperature (optional). It is applicable for spot-checking and/or continuous recording of SpO2, pulse rate and temperature of adult, pediatric and neonate patients in clinical institutions and homes.**
GMDN	**45607 Pulse oximeter**
EMDN code:	**Z1203020408: Pulse oximeters**
Risk class:	**Class IIa**
Basic UDI-DI	**69419006HPOximeter0102HN**
Conformity assessment procedure:	**EU 2017/745 (MDR) Annex IX (Chapter I + III and Sec.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	**EU 2017/745 (MDR)**
Directives	**RED, 2014/53/EU** **ROHS, Directive 2011/65/EU with (EU) 2015/863**
Applicable CS or Standard(s)	**EN 60601-1: 2006+A1: 2013+A2: 2021** **EN 60601-1-2: 2015+A1: 2021** **EN 60601-1-6: 2010+A1: 2013+A2: 2021** **EN 60601-1-11: 2015+A1: 2021** **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 50663: 2017
EN 62479: 2010
ETSI EN 300 328 V2.2.2 (2019)
ETSI EN 301 489-1 V2.2.3 (2019)
ETSI EN 301 489-17 V3.3.1 (2024)
EN ISO 14971: 2019+A11-2021
EN ISO 13485: 2016+A11: 2021
EN ISO 15223-1: 2021
EN ISO 20417: 2021
EN 62304: 2006+A1: 2015
EN 62366-1: 2015+A1: 2020

Certificate No.:	**G15 049076 0019 Rev. 00**
Issue date:	**2026-02-13**
Expiry date:	**2031-02-12**
Notified Body:	**TÜV SÜD Product service GmbH** **Ridlerstraße 65 • 80339 Munich• Germany** **CE 0123**

Zhang Xiang

Shenzhen, 2026/02/13 — Zhang Xiang Management Representative

Place, date — Name and function