# DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC (INCLUDING DIRECTIVE2007/47/EC)CONCERNING MEDICAL DEVICES

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| **MANUFACTURER:** | Shenzhen Creative Industry Co., Ltd.<br>Floor 5, BLD 9, Baiwangxin High-Tech Industrial Park,<br>Songbai Road, Xili Street, Nanshan District,<br>518110 Shenzhen, PEOPLE'S REPUBLIC OF CHINA |
| **MEDICAL DEVICE:** | Handheld Pulse Oximeter |
| **MODEL:** | SP-20 |
| **CLASSIFICATION - ANNEX IX:** | Class IIa, Rule 10 |
| **GMDN CODE:** | 45607 |
| **CONFORMITY ASSESSMENTROUTE:** | Annex II excluding(4) |

WE, **Shenzhen Creative Industry Co., Ltd.**, HEREWITH DECLARE THAT THE STATED MEDICAL DEVICESMEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 (AMENDED BY DIRECTIVE 2007/47/EC) CONCERNING MEDICAL DEVICES;ALL SUPPORTING DOCUMENTATION ARE RETAINED UNDER THE PREMISES OF THE MANUFACTURER. WE ARE EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY.

**STANDARDS APPLIED:**

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| ENISO 13485: 2016 | ENISO 14971: 2012 | IEC 60601-1: 2005+A1: 2012 |
| IEC 60601-1-2: 2014 | IEC 60601-1-6: 2010+A1:2013 | IEC 60601-1-11: 2015 |
| ISO 80601-2-61: 2017 | EN ISO 15223-1: 2016 | EN ISO 10993-1: 2009/AC:2010 |
| EN ISO 10993-5: 2009 | EN ISO 10993-10: 2013 | EN 14155: 2011 |
| EN 1041: 2008+A1: 2013 | | |

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| **NOTIFIED BODY:** | TÜV SÜD Product Service GmbH .<br>Ridlerstraβe 65.80339 Munich.Germany |
| **IDENTIFICATION NUMBER** | 0123 |
| **(EC) CERTIFICATE(S):** | G1 049076 0016 Rev .03 |

EC REP

**EUROPEAN REPRESENTATIVE:** Shanghai International Holding Corp. GmbH (Europe)
Eiffestraβe 80, 20537 Hamburg, Germany

**START OF CE-MARKING:** OCT.15, 2010

**PLACE, DATE OF DECLARATION:** Shenzhen,Apr.8,2021

**SIGNATURE:**

**NAME:** Apr.8,2021

**POSITION:**Management Representative