

DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC (INCLUDING DIRECTIVE 2007/47/EC) CONCERNING MEDICAL DEVICES

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

MEDICAL DEVICE: SpO2 Probe

MODEL: KS-C01:15040009/15044074/15040022
KS-C02: 15040015/15040021/15040031/15040055
KS-R02: 15040054
KS-YW02: 15040017/15040033/15040019
KS-R01: 15040084/15040082
KS-CM01: 15044076; KS-CM02: 15040063
KS-AYW02: 15040078; KS-AC01: 15040077;
KS-AC02: 15040097/15040103
KS-AR01: 15040099; KS-AR02: 15040098

CLASSIFICATION - ANNEX IX: Class IIa, Rule 10

GMDN CODE: 36087

CONFORMITY ASSESSMENT ROUTE: Annex II excluding(4)

WE, **Shenzhen Creative Industry Co., Ltd.**, HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES MEET 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:

EN ISO 13485: 2016	EN ISO 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 1041: 2008+A1: 2013	ISO 10993-5: 2009
ISO 10993-10: 2010	EN 14155: 2011	EN ISO 15233-1: 2016

NOTIFIED BODY: TÜV SÜD Product Service GmbH.
Ridlerstraße 65.80339 Munich.Germany
IDENTIFICATION NUMBER 0123
(EC) CERTIFICATE(S): G1 049076 0016 Rev .03

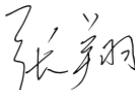


EUROPEAN REPRESENTATIVE: Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80, 20537 Hamburg, Germany

START OF CE-MARKING: 2014-12-09

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

SIGNATURE:

NAME:  Apr.8, 2021
POSITION: Management Representative