

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

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

MEDICAL DEVICE: SpO2 Probe

MODEL: KS-C01: 15040009/15040015/15040021/15044074/15040024/
15040031
KS-YW02: 15040017/15040019/15044923/15040073/
15040033
KS-R01:15040084/15040082/15040085
KS-R02:15040054/15040047
KS-AC01:15040155/15044901/15040077/15040091
KS-AC02: 15040097
KS-AR01:15040099/15040083/15040157
KS-AR02:15040156/15044906/15040098
KS-AYW02:15040078/15040092
KS-ALW02S: 15040128
KS-AE01: 15040129/15040154/15044812
KS-CM01: 15040169/15040063

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: 2019	IEC 60601-1: 2005+A1: 2012+A2:2020
IEC 60601-1-2: 2014+A1:2020	IEC 60601-1-6: 2010+A1:2013+A2:2020	IEC 60601-1-11: 2015+A1:2020
ISO 80601-2-61: 2017	ISO 10993-5: 2009	EN ISO 10993-10:2023
ISO 10993-23: 2021	EN ISO 14155:2020	EN ISO 15223-1: 2021

NOTIFIED BODY: TÜV SÜD Product Service GmbH .
Ridlerstraße 65.80339 Munich.Germany

IDENTIFICATION NUMBER 0123

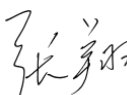
(EC) CERTIFICATE(S): G1 049076 0016 Rev .03

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, Dec 10, 2024

SIGNATURE:

NAME:  Dec 10, 2024
POSITION: Management Representative