DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC (INCLUDING DIRECTIVE2007/47/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-C01:15040009/15044074/15040022/15040015/ 15040021/15040031/15040055 KS-R02: 15040054 KS-YW02: 15040017/15040033/15040019/15044923 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 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:

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 . 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: 2014-12-09

PLACE, DATE OF DECLARATION: Shenzhen,Nov.13,2023

SIGNATURE:

NAME: Nov. 13, 2023

POSITION: Management Representative