

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

<b>MANUFACTURER:</b>	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	
<b>MEDICAL DEVICE: Model:</b>	SpO <sub>2</sub> Probe KS-C01: 15040009/15044074 KS-C02: 15040015/15040021/15040031 KS-R02: 15040054 KS-YW02: 15040017/15040033 KS-LW02: 15040032 KS-R01: 15040084 KS-CM01: 15044076 KS-CM02: 15040063 KS-AYW02: 15040078 KS-AC01: 15040077 KS-AR02: 15040098	
<b>CLASSIFICATION - ANNEX IX:</b>	Class IIa, Rule 10	
<b>CONFORMITY ASSESSMENT ROUTE:</b>	Annex II excluding(4)	
<p>WE, <b>Shenzhen Creative Industry Co., Ltd.</b>, 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/EEC) CONCERNING MEDICAL DEVICES; ALL SUPPORTING DOCUMENTATION ARE RETAINED UNDER THE PREMISES OF THE MANUFACTURER. WE ARE EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY.</p>		
<b>STANDARDS APPLIED:</b>		
EN/ISO 13485: 2016	EN/ISO 14971: 2012	EN 60601-1: 2006+A1: 2013
EN 60601-1-2: 2014	EN 60601-1-6: 2010	IEC 60601-1-11: 2015
ISO 80601-2-61: 2011	EN ISO 10993-1: 2009	EN ISO 10993-5: 2009
EN ISO 10993-10: 2010	EN 14155: 2011	EN 1041: 2008
ISO 15233-1: 2016	2011/65/EU	
<b>NOTIFIED BODY:</b>	TÜV SÜD PRODUCT SERVICE GMBH RIDLERSTR 65, D-80339 MÜNCHEN, GERMANY	
<b>IDENTIFICATION NUMBER</b>	0123	
<b>(EC) CERTIFICATE(S):</b>	G1 049076 0016 REV. 02	
<b>EC REP</b>		
<b>EUROPEAN REPRESENTATIVE:</b>	Shanghai International Holding Corp. GmbH (Europe) Eiffestraße 80, 20537 Hamburg, Germany	
<b>START OF CE-MARKING:</b>	2014-12-09	
<b>PLACE, DATE OF DECLARATION:</b>	Floor 5, BLD 9, Baiwangxin High-Tech Industrial Park, Songbai Road, Xili Street, Nanshan District, 518110 Shenzhen, PEOPLE'S REPUBLIC OF CHINA	
<b>SIGNATURE:</b>	 <b>NAME:</b> 张翔      FEB 05, 2020 <b>POSITION:</b> Management Representative	