

	EU Declaration of Conformity	Document No.	CETF attachment 2
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	SpO2 Sensors	Version	1.0

DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES

Manufacturer	Name: Shenzhen Medke Technology Co., Ltd. Address: 4/F, Bldg. A1, Anle Ind. Zone, Hangcheng RD., Baoan Dist., Shenzhen, China 518126			
Authorised Representative	Name: Shanghai International Holding Corp. GmbH (Europe) Address: Eiffestrasse 80, 20537 Hamburg, Germany SRN: DE-AR-000000001			
Product Name	SpO2 Sensors			
Model	P3119 , P4119, P5119, P6119, P7119, P8119, P9119			
CND Code	C900301 SENSORI PER OSSIMETRIA			
GMDN Code	17594			
Basic UDI-DI	P3119	697101811P31193U	P5119	697101811P51194A
	P4119	697101811P411943	P6119	697101811P61194H
	P9119	697101811P911956	P7119	697101811P71194Q
	P8119	697101811P81194X		
Device Photograph	Please refer to 2.1.3 Main introduction of Medke SpO2 sensors in TCF - SPO2 Sensor_V1.3 Device Description and Specification.			
Intended Purpose	SpO2 sensors are indicated for use in continuous noninvasive monitoring of arterial oxygen saturation and pulse rate. They are fully compatible replacement sensors intended for use with major brands of pulse oximeter. The SpO2 sensor is designed to match the specifications of the original equipment manufacturer, therefore ensure the appropriate sensor model number is selected for a particular pulse oximeter technology.			
Risk Class	Class IIb			
Classification Rule	According to Rule 10			
Conformity Assessment Route	Annex II excluding 4			
We, the manufacturer, herewith declare under our sole responsibility that the stated medical devices meet the transposition into national law, the provisions of Council Directive 93/42/EEC concerning medical devices; All supporting documentation is retained at the premises of the manufacturer.WE are exclusively responsible four this doc.				
Applied Standards	ISO 80601-2-61:2011, ISO 10993-1:2009, ISO 10993-5:2009, ISO 10993-10:2010 , EN60601-1-2:2014, EN 60601-1:2006/A1:2013, ISO15233-1:2016, EN ISO 14971:2012			
Place, Date of Issue	Shenzhen, Guangdong 2021-06-23			
Signature:	<div> Name: Zuyin Xian Function: General Manager</div> <div></div>			