Declaration of Conformity to Council Directive 93/42 EEC (Including Directive 2007/47/EEC) Concerning Medical Devices

For the following products:

Spo2 sensor

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 of 14 June, 1993, concerning medical devices; including, at 21 March, 2010, the amendments by Council Directive 2007/47/EEC. All supporting documentation is retained at the premises of the manufacturer.

The validity period of this declaration of conformity is limited by the issuing of a revised declaration of conformity after change of the product and/or by the expiration date of the related Annex II certificate issued by the notified body.

The manufacturer is exclusively responsible for the DoC, which is preserved in documental control center.

EC Certificate
NO.G10047170002 REV.00
Report NO :GZ1834801
TUV SUD approved
UDI number:697531983YKD003RN

Harmonized standards:

EN ISO14971:2012; EN ISO 15223-1:2016; EN 1041:2008; EN 60601-1:2006/A1:2013; EN 60601-1-2:2015; EN 60601-1-6:2010, EN ISO 10993-1:2009, EN ISO 10993-5:2009, EN ISO 10993-10:2010; EN 62366:2008; ISO 80601-2-61:2011

Conformity Assessment Route: According to 93/42/EEC, Annex II, excluding section 4.

Classification (93/42/EEC, Annex IX): Class IIB

The following representative in Europe is responsible for making this declaration:

Company Name: Luxus Lebenswelt GmbH
Company Address: Kochstr, 1, 47877, Willich, Germany

The following manufacturer is responsible for making this declaration:

Manufacturer Name: Shenzhen YKD technology Co., Ltd.

Address: 6F, Building 6, Huaxinruiming Industrial Area, Langrong RD, Xinwei Village, Dalang Community, Dalang Street, Longhua District, Shenzhen

Notified Body:

Company Name: TÜV SÜD Product Service GmbH
Company Address: Ridlerstrasse 65, 80339 Munchen, Germany
Website: www. tuv-sud.com

Notified Body number: CE 0123

	General Manager	Shenzhen	2022-04-12
(Legal Signature)	(Position/title)	(Place)	(Date)