Redy-Med
瑞迪迈科技

EU DECLARATION OF CONFORMITY

TO COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES

Declaration Number:	RDM-CE-02-004 REV: A/3 Date: 2020.02.30
The Manufacturer:	Shenzhen Redy-Med Technology Co., Ltd. Rm 803, #4 Building,Xianan 3rd Ind Pk, Gongming Street, Guangming New District,Shenzhen, China.
European Representative:	Wellkang Ltd. Enterprise Hub, NW Business Complex,1Beraghmore Rd, Derry, BT 48 8SE Northem Ireland,UK Tel: +44 (20)3287 6300, 3303 1126 Fax: +44(20)76811874 Email: AuthRep@CE-marking.eu Web:www.wellkang .lid .uk/www.CE-Marking.eg
Product Name:	SpO_2 Sensors The SpO_2 Sensor is intended to be used for continuous, non-invasive functional arterial oxygen saturation (SpO2) and pulse rate monitoring of patients.
Models:	RD130F-29 and RD130S-29
Classification:	Class IIb, Rule 10
Conformity Assessment Route:	ANNEX II, Section 3, of MDD 93/42/EEC, as amended by Directive 2007/47/EC

We herewith declare under our sole responsibility that the above mentioned products meet the transposition into national law and the provisions of council Directive 93/42/EEC of 14 June 1993, as amended by Directive 2007/47/EC. All supporting documentation is retained at the premises of the manufacturer.

Standards Applied:

EN ISO 13485: 2016; EN ISO 14971: 2012; EN 1041:2008+A1:2013; EN ISO 15223-1:2016; EN 60601-1-6:2010+A1:2015; EN 62366-1:2015; EN 60601-1:2006+A1:2013; EN 60601-1-2:2015; EN ISO 80601-2-61: 2011; EN 62471:2008; EN ISO 10993-1:2009/AC: 2010; EN ISO 10993-5:2009; EN ISO 10993-10:2009 and EN ISO 14155:2011/AC:2011.

Notified Body:	SGS FIMKO OY, Takomotie 8 00380 HELSINKI Finland Phone: +358 9 696361 Fax: E-MAIL: nb.fimko@sgs.com Website:www.sgs.fi
Identification Number:	**0598**
EC Certificate Number:	**FI20/07002**
Start of CE-Marking:	**2020.04.01**
Place, Date of Issue:	Shenzhen, JFeb 30,2019
Signature:	Jinlong Wu
Name:	**Jinlong Wu**
Title:	**General Manager**