

EC Certificate Full Quality Assurance System Fl20/07002

The management system of

## ShenZhen Redy-Med Technology Co., Ltd

Rm 803, #4 Building, Xia'nan 3rd Ind Pk, Gongming Str., Guangming New District Shenzhen, P.R.China

has been assessed and certified as meeting the requirements of

## **Directive 93/42/EEC**

on Medical Devices, Annex II (excluding section IV)

For the following products

SpO<sub>2</sub> Sensors

Products covered are listed in Attachment 1 of this certificate

This certificate is valid from 18 February 2020 until 26 May 2024 and remains valid subject to satisfactory surveillance audits. Issue 1. Certified since 18 February 2020 This certification is based on decision: FI20/07002P0

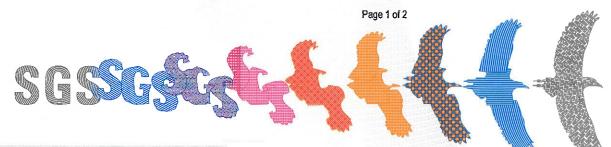
FINAS
Finnish Accreditation Service
\$003 (EN ISO/IEC 17065)

Authorised by

Seppo Vahasalo Notified Body Manager

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## Attachment 1 to SGS Fimko Ltd. EC certificate FI20/07002 Issue 1

Manufacturer	ShenZhen Redy-Med Technology Co., Ltd
Address	Rm 803, #4 Building, Xia'nan 3rd Ind Pk, Gongming Str., Guangming New District Shenzhen, P.R.China
Activity and Medical Device Product Category	93/42/EEC Annex II (excluding Section 4) SpO <sub>2</sub> Sensors

List of medical devices and the corresponding type/model markings with product trademarks/marketing names covered by this certificate:

Medical Device	Class	Trademark(s) and Model(s)/type(s)
SpO <sub>2</sub> Sensor	llb	RD130F-29
SpO <sub>2</sub> Sensor	lib	RD130S-29

18 February 2020

FI20/07002P0



ShenZhen Redy-Med Technology Co., Ltd Rm 803, #4 Building, Xia'nan 3rd Ind Pk, Gongming Str., Guangming New District Shenzhen, P.R.China

## EC-certification application 18/081-0

Certification of quality system and product range, based on Council Directive Subject

93/42/EEC concerning medical devices, Annex II Section 3 (excluding Section

Manufacturer ShenZhen Redy-Med Technology Co., Ltd

Rm 803, #4 Building,

Xia'nan 3rd Ind Pk, Gongming Str., Guangming New District Shenzhen,

P.R.China

A certificate will be issued for the manufacturer. The certificate covers the Decision

following products:

Product	Model	Class
SpO <sub>2</sub> Sensor	RD130F-29	IIb
SpO <sub>2</sub> Sensor	RD130S-29	Ilb

Justification SGS Fimko Ltd has assessed manufacturer's quality management system

and products. Quality management system and products meet the

requirements of Annex II (excluding Section 4) of Medical Device Directive 93/42/EEC. The decision is based on audit report(s) 293260, dated 2019-10-

The manufacturer has signed the undertaking to follow the obligations of

Annex II of the Directive 93/42/EEC.

Certificate related to decision

FI20/07002, issue 1

Attachment to certificate

Attachment 1

Valid until This decision is valid until 17 February 2025 providing the requirements of the

certification are fulfilled.

Date Helsinki, 18 February 2020

Seppo Vahasalo, Notified Body Manager

SGS Fimko Ltd, Notified Body 0598