EC Certificate Full Quality Assurance System FI20/07002

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_2 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
S003 (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_2 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_2 Sensor	IIb	RD130F-29
SpO_2 Sensor	IIb	RD130S-29

DECISION

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

Subject	Certification of quality system and product range, based on Council Directive 93/42/EEC concerning medical devices, Annex II Section 3 (excluding Section 4)
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
Decision	A certificate will be issued for the manufacturer. The certificate covers the following products:

Product	Model	Class
SpO_2 Sensor	RD130F-29	IIb
SpO_2 Sensor	RD130S-29	IIb

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 2019-10-18 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