EC Declaration of Conformity

Product Description	Product Name	Class
Pulse Oximeter	Unit: SA110, SA120, SA200, SA210, SB100, SB200, SB210, SB220, SA300, SA310, SA320, SD100 Probe: PA100, PB100, PC100, PD100, PF100	IIb

Is herewith confirmed to comply with the requirements set out in the Council Directive on the harmonization of the laws of Member States concerning **Medical Devices Directive 93/42/EEC as amended by 2007/47/EC** with the compliance of conformity assessment Annex II-exclusive section 4 to be certified by **DNV Product Assurance AS (notify body number –2460), address: Veritasveien 3, 1363 Høvik, Norway.**

The products compliance with the essential requirements in accordance with Annex I of the Medical Devices Directive 93/42/EEC.

For the evaluation regarding the **Class IIb** product safety aspects, the following harmonized standards are applied: EN ISO13485:2016; ISO80601-2-61:2017; ISO14971:2019; ISO/TR24971:2020; EN ISO15223-1:2016;
EN 1041:2008; EN 60601-1:2006/A1:2013; EN 60601-1-2:2015;
IEC 60601-1-6:2010/A1:2013/A2:2020; IEC 60601-1-11:2015; ISO10993-1:2018; EN ISO10993-5:2009; ISO10993-10:2010; EN 62366-1:2015/A1:2020; EN 62304:2006/A1:2015;

The following European Authorized Representative is stated to the declaration:

Representative Name: **CMC Medical Devices & Drugs S.L.**

Representative Address : **C/ Horacio Lengo Nº 18, CP 29006, Málaga, Spain**

The following Swiss Authorized Representative is stated to the declaration:

Representative Name: **QS Engineering AG**

Representative Address : **Erlenstrass31 CH-4106 Therwil, Switzerland**

The following person is exclusive responsible for the compliance of declaration:

Manufacturer Name : **Rossmax Innotek Corp**

Head office : **12F., No. 189, Kang Chien Rd, Taipei 114, Taiwan**

Manufacturing site: **1F/6F., No. 789, Bo-Ai St., Jhubei City, Hsinchu County 302, Taiwan.**

President		**January 27, 2022**
(Position / Title)	(Legal Signature)	(Date)

DNV

EC CERTIFICATE
Full Quality Assurance System

Certificate no.:	Initial certification date:	Valid Until:
10647-2017-CE-RGC-NA-PS Rev 1.0	12 June 2018	12 June 2023

This is to certify that the management system of

Rossmax Innotek Corp.
12F, No. 189, Kang Chien Rd., Taipei 11494, Taiwan

For design, production and final product inspection/testing of:
Pulse Oximeter

has been assessed and found to comply with respect to:
the conformity assessment procedure described in Annex II excluding section 4 of Council Directive 93/42/EEC on Medical Devices, as amended

Place and date:
Høvik, 18 May 2021

For the issuing office:
DNV Product Assurance AS - Notified Body 2460
Veritasveien 3, 1363 Høvik, Norway

Veena Gunashekaran

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift om Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate History		
Revision	**Description**	**Issued Date**
0.0	New issued	2018-06-12
1.0	Editorial Changes and blockchain information	2021-05-18

Products covered by this Certificate:		
Product Description	**Product Name**	**Class**
Pulse Oximeter	Unit: SA110, SA120, SA200, SA210, SB100, SB200, SB210, SB220, SA300, SA310, SA320, SD100 Probe: PA100, PB100, PC100, PD100, PF100	IIb

Sites covered by this certificate	
Site Name	**Site Address**
Rossmax Innotek Corp. - Taipei	12F, No. 189, Kang Chien Rd., Taipei 11494, Taiwan
Rossmax Innotek Corp. - Hsinchu	1F & 6F, No. 789, Bo-Ai St., Jhubei City, Hsinchu County 30265, Taiwan

EU Representative
CMC Medical Devices & Drugs S.L. C/ Horacio Lengo Nº 18, CP 29006, Málaga, Spain

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform the Notified Body of any intended updating of the quality system and the Notified Body will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Notified Body reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number.