



# EC Certificate

## Full Quality Assurance System

Certificate No.:  
**10647-2017-CE-RGC-NA-PS Rev. 0.0**

Project No.:  
**PRJC-10388-2007-PRC-RGC**

Valid Until:  
**12 June 2023**

This is to certify that the quality 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 with respect to:

**The conformity assessment procedure described in Article 11.3.a and Annex II excluding section 4 (Module H) of Council Directive 93/42/EEC on Medical Devices, as amended**

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and Date:  
**Høvik, 12 June 2018**



For:  
**DNV GL NEMKO PRESAFE AS**

*Tone Kolpus*

**Tone Kolpus**

The Certificate has been digitally signed.  
See [www.presafe.com/digital\\_signatures](http://www.presafe.com/digital_signatures) for more info

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.



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### Jurisdiction

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

### Certificate history:

Revision	Description	Issue Date
	New issued	2018-06-12

### 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

The complete list of devices is filed with the Notified Body

### Sites covered by this certificate

Site Name	Address
Head office	12F, No. 189, Kang Chien Rd., Taipei 11494, Taiwan
Manufacturing site.	1F & 6F, No. 789, Bo-Ai St., Jhubei City, Hsinchu County 30265, Taiwan

### EU Representative

Site Name	Address
CMC Medical Devices & Drugs S.L.	C/ Horacio Lengo Nº 18, CP 29006, Málaga, Spain



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### 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 Presafe of any intended updating of the quality system and Presafe 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. Presafe 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 of Presafe.

End of Certificate



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

DNV  
29Fl., No. 293, Sec. 2,  
Wenhua Rd., Banchiau  
Dist., New Taipei City,  
Taiwan 220, R.O.C.  
Tel: +886 2 82537800  
Fax: +886 2 82537666

**Date:** 2023-10-18  
**Our reference:** PRJC-10388-2007-PRC-RGC  
**Your reference:** 10647-2017-CE-RGC-NA-PS Rev 1.0

## Confirmation Letter

**Company Name:**  
Rossmax Innotek Corp.

**Conformity Assessment :**  
Annex II excl. section 4 of Council Directive 93/42/EEC on Medical Devices, as amended

**Site Address :**  
12F, No. 189, Kang Chien Rd., Taipei 11494, Taiwan

**Product Description:**  
Pulse Oximeter

**Product Name:**  
Unit:  
SA110, SA120, SA200, SA210, SB100, SB200,  
SB210, SB220, SA300, SA310, SA320, SD100  
Probe:  
PA100, PB100, PC100, PD100, PF100

**Certificate No.:**  
10647-2017-CE-RGC-NA-PS Rev 1.0

**Valid Until:**  
12 June 2023

**Status:**  
We, DNV, hereby confirm that Rossmax Innotek Corp. (legal manufacturer) have signed the MDR certification agreement with DNV in covered of the requirements of the implementation of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 as regards the transitional provisions for certain medical devices.

Dennis Lin  
DNV Business Assurance Co., Ltd, Product Assurance Director

