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)