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 82537699

Date:	Our reference:	Your reference:
2023-11-29	PRJC-10388-2007-PRC-RGC	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

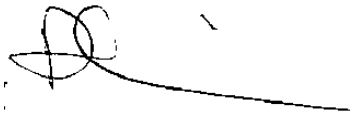
Status:
We, DNV, hereby confirm that Rossmax Innotek Corp. (legal manufacturer) have signed the MDR certification agreement with DNV in covered of the requirements of the implementation of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 as regards the transitional provisions for certain medical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

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3 of MDR (as amended by EU 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)

- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function.

- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)



Dennis Lin
DNV Business Assurance Co., Ltd, Product Assurance Director
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2023-11-29