# EU Quality Management System Certificate

Certificate no.:
C763229

Initial certification date:
05 January 2026

Valid Until:
05 January 2031

This is to certify that the quality system of

## Sky Labs Inc.

#702, #703, 58, Pangyo-ro 255beon-gil, Bundang-gu, Seongnam-si, Gyeonggi-do, 13486, Republic of Korea

SRN: KR-MF-000026801

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

**Vital Signs Monitoring Instruments and Blood Pressure Monitoring Instruments**

Has been assessed and found to comply with respect to:

**The conformity assessment procedure described in Annex IX, (Chapter I & III) of Regulation (EU) 2017/745 on Medical Devices**

Place and date:
**Høvik, 01 October 2026**

For the issuing office:
**DNV Product Assurance AS – Notified Body 2460**
**Veritasveien 1, 1363 Høvik, Norway**

C. Rajesh Kumar

**Rajesh Kumar Chellappan**
Management Representative

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

NOTIFIED BODY 2460: DNV Product Assurance AS, Veritasveien 1, 1363 Høvik, Norway, Tel +47 67 57 88 00, www.dnv.com

Certificate no.: C763229
Place and date: Høvik, 01 October 2026

## Jurisdiction

Application of Regulation 2017/745 on medical devices, implemented in Norway by Act 7 May 2020 no. 37 on medical devices and Regulation 9 May 2021 no.1476 on medical devices by the Norwegian Ministry of Health and Care Services.

Certificate history:

| Revision | Description | Report No. | Issue Date |
|---|---|---|---|
| 0.0 | Original Certificate | 2540810 | 05 January 2026 |
| 1.0 | Scope Extension and Model Addition | 3546592 | 01 October 2026 |

Products covered by this Certificate:

| Product Description (and intended purpose for class IIb) | Product Name | Class* |
|---|---|---|
| VITAL SIGNS MONITORING INSTRUMENTS | CART PLATFORM (Model Name: CART-I RING and CART-I CRADLE) | IIa |
| VITAL SIGNS MONITORING INSTRUMENTS - SOFTWARE | CART PLATFORM (Model Name: CART-APP and CART-SERVER) | IIa |
| VITAL SIGNS MONITORING INSTRUMENTS - SOFTWARE | CART PLATFORM (Model Name: CART-WEB and CART-SERVER) | IIa |
| BLOOD PRESSURE MONITORING INSTRUMENTS | CART BP pro (Model Name: CART-RING and CART-CRADLE) | IIa |
| BLOOD PRESSURE MONITORING INSTRUMENTS - SOFTWARE | CART BP pro (Model Name: CART BP pro-APP and CART-SERVER) | IIa |
| BLOOD PRESSURE MONITORING INSTRUMENTS | CART BP (Model Name: CART-RING and CART-CRADLE) | IIa |
| BLOOD PRESSURE MONITORING INSTRUMENTS - SOFTWARE | CART BP (Model Name: CART BP-APP and CART-SERVER) | IIa |

* Class III and class IIb devices referred to in the second subparagraph of Article 52(4): Technical documentation assessment is covered by a separate EU Technical Documentation Assessment Certificate No.: N/A

The complete list of devices is filed with the Notified Body

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## Sites covered by this certificate

| Site Name | Address |
|---|---|
| Sky Labs Inc. | #702, #703, 58, Pangyo-ro 255beon-gil, Bundang-gu, Seongnam-si, Gyeonggi-do, 13486, Republic of Korea |

| EU Representative |
|---|
| Obelis s.a., Boulevard Général Wahis 53, B-1030 Brussels, Belgium |

SAFEGUARDING LIFE, PROPERTY AND THE ENVIRONMENT - DNV 1864

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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 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.
- For the class III devices and IIb devices falling under Article 52 (4) covered this certificate is dependent on the continued validity of the EU Technical Documentation Assessment Certificate, covering the devices.

The following may render this Certificate invalid:

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

## Specific conditions - Class I devices, Systems and Procedure Packs:

- For class I device being placed on the market in a sterile condition, Class I devices with a measurement function and class I devices being reusable surgical instruments covered by this certificate the audit by the notified body of the quality management system was limited to the aspects required under article 52(7) of the regulation.
- For system and procedure packs being placed on the market in a sterile condition, covered by this certificate the audit by the notified body of the quality management system was limited to the aspects required under article 22(3) of the regulation.
- For Custom Made Class III implantable device the certification only relates to the Quality management system. Technical documentation assessment and issuance of EU Technical Documentation Assessment Certificate does not apply.