



DNV

MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:
10000501565-PA-MDSAP-TWN

Initial certification date:
2019-12-20

Expiry Date:
2028-11-19

This is to certify that the management system of

Hsiner Co., Ltd.

No. 312, Jhongshan Rd., Shengang Dist., Taichung City 429, Taiwan

F005856

and the sites as mentioned in the appendix accompanying this certificate

has been found to conform to the Quality Management System standard:

ISO 13485:2016 and the requirements of the following regulatory authorities

Australia:

- Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure

Brazil:

- RDC ANVISA n. 665/2022
- RDC ANVISA n. 551/2021
- RDC ANVISA n. 67/2009

Canada:

- Medical Devices Regulations – Part 1- SOR 98/282

Japan:

- MHLW Ministerial Ordinance 169, Article 4 to Article 68
- PMD Act

United States:

- 21 CFR 803
- 21 CFR 806
- 21 CFR 807 – Subparts A to D
- 21 CFR 820

This certificate is valid for the following scope:

Design and Manufacture of Sterile and Non-Sterile Anaesthesia/Breathing Systems, Anaesthesiology Products, Oxygen Therapy Products, Aerosol Therapy Products and Ear Suction Bulb. Design and Manufacture of Non-Sterile Anaesthesia Masks, Ventilation Masks, CPAP Masks, Emergency Masks, Respiratory Care Products, Sleep Therapy Products, Anaesthesiology Products, Oxygen Therapy Products, Aerosol Therapy Products, Resuscitator Products and Oral Appliance.

Place
Høvik

Effective Date:
2026-02-04



DNV Product Assurance AS is an MDSAP
Recognized Auditing Organization

For the issuing office:

DNV Product Assurance AS
Veritasveien 1, 1363 Høvik, Norway

Hazem Tinawi
Management Representative

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

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

Your certificate is stored in DNV's secure certificate storage, providing traceability and trust to further enhance the value of your certification. Anyone can easily verify the validity of a certificate and details through the QR code on the certificate or in the link, <https://certificatechecker.dnv.com/> with the certificate number/manufacturer name.

Appendix to Certificate

Locations included in the certification are as follows:

Site Name	Site Address	Site Scope
Hsiner Co., Ltd. F005856	No. 312, Jhongshan Rd., Shengang Dist., Taichung City 429, Taiwan	Design and Manufacture of Sterile and Non-Sterile Anaesthesia/Breathing Systems, Anaesthesiology Products, Oxygen Therapy Products, Aerosol Therapy Products and Ear Suction Bulb. Design and Manufacture of Non-Sterile Anaesthesia Masks, Ventilation Masks, CPAP Masks, Emergency Masks, Respiratory Care Products, Sleep Therapy Products, Anaesthesiology Products, Oxygen Therapy Products, Aerosol Therapy Products, Resuscitator Products and Oral Appliance.
Hsiner Co., Ltd. F008630	No. 251, Sec. 1, Houke Rd., Houli Dist., Taichung City 421, Taiwan	Manufacture of Non-Sterile Anaesthesia Masks, Ventilation Masks, CPAP Masks, Emergency Masks, Respiratory Care Products, Sleep Therapy Products, Anaesthesia/Breathing Systems, Anaesthesiology Products, Oxygen Therapy Products, Aerosol Therapy Products, Resuscitator Products and Oral Appliance.