

MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:
248759-2017-AQ-RGC-NA-PS

Initial certification date:
18 January 2018

Valid:
26 November 2025 – 18 January 2027

This is to certify that the management system of

Hsiner Co., Ltd.

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

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 / EN ISO 13485:2016

This certificate is valid for the following scope:

Design, Manufacture, Sales and Distribution of Non-Sterile Anaesthesia Masks, Ventilation Masks, CPAP Masks, Emergency Masks, Sleep Therapy Products, Resuscitator Products. Design, Manufacture, Sales and Distribution of Sterile and Non-Sterile Anaesthesia/Breathing Systems, Oxygen Therapy Products, Aerosol Therapy Products and Oropharyngeal Airway Products.

Manufacture, Sales and Distribution of Non-Sterile Oral appliance.

Manufacture, Sales and Distribution of Sterile and Non-Sterile Ear Suction Bulb.

Manufacture, Sales and Distribution of Non-Sterile Anaesthesia Masks, Ventilation Masks, CPAP Masks, Emergency Masks, Sleep Therapy Products, Resuscitator Products, Anaesthesia/Breathing Systems, Oxygen Therapy Products, Aerosol Therapy Products and Oropharyngeal Airway Products.

Place and date:
Høvik, 26 November 2025



For the issuing office:
DNV Product Assurance AS
Veritasveien 1, 1363 Høvik, Norway

Cecilie Gudesen Torp

Cecilie Gudesen Torp
Management Representative



DNV

Certificate no.: 248759-2017-AQ-RGC-NA-PS
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Appendix to Certificate

Hsiner Co., Ltd.

Locations included in the certification are as follows:

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