CERTIFICATE OF REGISTRATION

This is to certify that

Hsiner Co. Ltd.

No.312, Jhongshan Rd., Shengang Dist., Taichung City 429, Taiwan
D-U-N-S: 657310868

operates a

Quality Management System

which complies with the requirements of

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

Australia:
- Therapeutic Goods (Medical Devices) Regulations 2002: Schedule 3, Part 1 - Full Quality Assurance System

Brazil:
- RDC ANVISA n. 16/2013 - Good Manufacturing Practices
- RDC ANVISA n. 2/2012
- RDC ANVISA n. 67/2009 - Vigilance

Canada:
- Medical Device Regulations SOR/98-282, Part 1

Japan:
- MHLW Ministerial Ordinance No. 169 (2004) as amended by MHLW Ordinance No. 128 (2014) Articles 4 to 68
- Japan PMD Act (as applicable)

United States:
- 21 CFR Part 803 - Medical Device Reporting
- 21 CFR Part 806 - Reports of Corrections and Removals
- 21 CFR Part 807 (Subparts A to D) - Establishment Registration and Device Listing
- 21 CFR Part 820 - Quality System Regulation

for the following scope of certification

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

Certificate No.:	CERT-0126260	Original Certification Date:	2019-11-20
File No.:	1066898	Certification Effective Date:	2019-11-20
Issue Date:	2019-12-20	Certificate Expiry Date:	2022-11-19

Heather Mahon
Global Head of Technical Services SAI Global Assurance

ISO 13485:2016

SAI Global is an MDSAP authorized auditing organization.
MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

SAI GLOBAL

登録番号 BG10600023
Number of registration

医療機器　外国製造業者登録証

Registration certificate of foreign medical device manufacturer

氏名又は名称 Name (Name of corporation)	Hsiner Co., Ltd.
製造所の名称 Name of the manufacturing establishment	Hsiner Co., Ltd.
製造所の所在地 Location of the manufacturing establishment	No. 312. Jhongshan Rd., Shengang District. Taichung City, Taiwan, R. O. C

医薬品、医療機器等の品質、有効性及び安全性の確保等に関する法律第23条の2の4の規定により登録された医　療　機　器外国製造業者であることを証明する。

It is certified that the above manufacturer is certificated foreign medical device manufacturer pursuant to Article 23-2-4 of the Act on Pharmaceuticals and Medical Devices.

平成　28　年　11　月　15　日
2016　Year　Month　Day

厚生労働大臣 塩崎　恭久
Minister of Health, Labour and Welfare　Yasuhisa Shiozaki

有効期間　平成　29　年　2　月　2　日　から
Valid period　From　2017　Year　Month　Day

平成　34　年　2　月　1　日　まで
until　2022　Year　Month　Day

5122878010821

EC Certificate
Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
10240-2017-CE-RGC-NA-PS Rev. 2.0	PRJC-21611-2007-PRC-RGC	12 November 2023

This is to certify that the quality system of:

Hsiner Co., Ltd.
No. 312, Jhongshan Rd., Shengang District, Taichung City, Taiwan

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

Respiratory Devices

Has been assessed with respect to:

The conformity assessment procedure described in Annex II excluding section 4 of Council Directive 93/42/EEC on Medical Devices, as amended

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and Date:
Høvik, 08 July 2019

NORWEGIAN ACCREDITATION
PROD 021
Notified Body No.: 2460

For:
DNV GL PRESAFE AS

Sholeh Gheissar

Sholeh Gheissar

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info

EC Certificate
Full Quality Assurance System

Certificate No.:
10240-2017-CE-RGC-NA-PS Rev. 2.0

Project No.:
PRJC-21611-2007-PRC-RGC

Valid Until:
12 November 2023

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift om Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Original Certificate	2017-06-17
1.0	Re-certification	2019-05-23
2.0	**Revise address**	**2019-07-08**

Products covered by this Certificate:

Product Description	Product Name	Class
Respiratory Devices	- CPAP and VPAP Face Mask and Accessories (Reusable) - Oxygen Therapy and Accessories - Aerosol Therapy Devices - Anaesthesia and Breathing Circuit System and Accessories (Reusable) - Resuscitator and Accessories (Reusable) - HME and HMEF - Filter - CPAP VPAP Nasal Mask and Accessories (Reusable) - Anaesthesia and Breathing Circuit System and Accessories (Single-use) - Resuscitator and Accessories (Single-use)	IIa

The complete list of devices is filed with the Notified Body

EC Certificate
Full Quality Assurance System

Certificate No.:
10240-2017-CE-RGC-NA-PS Rev. 2.0

Project No.:
PRJC-21611-2007-PRC-RGC

Valid Until:
12 November 2023

Sites covered by this certificate

Site Name	Address
Hsiner Co., Ltd.	No. 312, Jhongshan Rd., Shengang District, Taichung City, Taiwan

EU Representative

Name	Address
mdi Europa GmbH	Langenhagener Strasse 71, 30855 Langenhagen, Germany

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 Presafe of any intended updating of the quality system and Presafe 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. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

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

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate

DNV·GL

MANAGEMENT SYSTEM CERTIFICATE

Certificate No.:	Project No.:	Initial Certification Date:	Valid Until:
248759-2017-AQ-RGC-NA-PS Rev 2.0	PRJC-21602-2007-MSC-RGC	18 January 2018	18 January 2021

This is to certify that the management system of:

Hsiner Co., Ltd

No. 312, Jhongshan Rd. Shengang District, Taichung City, Taiwan

Complies with the requirements of:
ISO 13485:2016/NS-EN ISO 13485:2016

The 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, Aerosol Therapy Products, and Oral Appliance.
Design, Manufacture, Sales and Distribution of Sterile and Non-Sterile Anaesthesia/Breathing Systems and Oxygen Therapy Products.

Place and date:
Høvik, 17 February 2020

NORWEGIAN ACCREDITATION
MSYS 018

For:
DNV GL PRESAFE AS

Eugenie Winger Husebye
Eugenie Winger Husebye

The certificate is digitally verified by blockchain technology. For more info, see www.dnvgl.com/assurance/certificates-in-the-blockchain.html