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

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

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

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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

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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

By Royal Charter

Supplementary information to AR120 817027

Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3

Issued to:

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

Date: 04 November 2025

Changes Approved:

Date	Reference Number	Action
03 December 2024	30269756	Transfer of appropriate surveillance to BSI per Regulation (EU) 2023/607 of: Oxygen Therapy and Accessories Aerosol Therapy Devices Anaesthesia and Breathing Circuit System and Accessories HME and HMEF Filter CPAP VPAP Mask and Nasal Mask and Accessories Original NB Certificate Number: 10240-2017-CE-RGC-NA-PS Rev 2.0
04 November 2025	30542838	Addition of critical subcontractor for design and manufacturing.

Inspiring trust for a more resilient world.

04 November 2025

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

To whom it may concern,

The transitional provisions specified in MDR Article 120(3) (as amended by (EU) 2023/607) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

The transitional provisions specified in IVDR Article 110(3) (as amended by (EU) 2024/1860) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing IVDD certificates from 26th May 2022.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) or under IVDR Article 110(3), as applicable, and as per the guidance provided in MDCG 2020-3/MDCG 2022-6.

The related certificate specified below continues to remain valid and devices can be placed on the market based on this certificate as long as the manufacturer complies with the conditions specified in Section 3c of Article 120 of MDR or in Section 3c of Article 110 of IVDR, as applicable.

Original certificate number	**BSI reference number**	**Directive and Annex**	**Reference Number**	**Changes approved**
10240-2017-CE-RGC-NA-PS	AR120 817027	93/42/EEC Annex II excluding Section 4	30542838	Addition of critical subcontractor for design and manufacturing.

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,

Graeme Tunbridge
Senior Vice President, Medical Devices

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