EC Certificate

TÜVRheinland®

Production Quality Assurance
Directive 93/42/EEC on Medical Devices, Annex V

Registration No.: DD 2017980-1

Manufacturer: Vapo Healthcare Co., Ltd.
Southern unit of third floor, building B
No. 99 Yudai West Rd, High tech district,
KunShan Suzhou
215301 Jiangsu
P.R. China

Products: Nebulizers, Infrared Forehead Thermometers, Electrical Thermometers

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Report No.: 17061663 010

Effective date: 2021-03-02

Expiry date: 2024-05-26

Issue date: 2021-03-02

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Dipl.-Ing. W. Hsu
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

EC Certificate

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Registration No.: DD 2017980-1

Manufacturer: Vapo Healthcare Co., Ltd.
Southern unit of third floor, building B
No. 99 Yudai West Rd, High tech district,
KunShan Suzhou
215301 Jiangsu
P.R. China

The scope of certification includes the following manufacturing sites:

No.	Location	Product groups manufactured
/01	Vapo Healthcare Co., Ltd. Room 1308, Industry Technology Institution, 1699 Zuchongzhi South BLVD, Kunshan, 215300 Jiangsu P.R. China	Nebulizers, Infrared Forehead Thermometers, Electrical Thermometers

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TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Vapo Healthcare Co., Ltd.
Southern unit of third floor
building B
No. 99 Yudai West Rd
High tech district
KunShan, Suzhou
215301 Jiangsu
P.R. China

has established and applies a quality management system for medical devices for the following scope:

Manufacture and Distribution of Nebulizers, Medicine Chamber Spacers, Infrared Forehead Thermometers (see attachment for additional site included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2020-03-02
Certificate Registration No.:	SX 60142378 0001
An audit was performed. Report No.:	17061663 006
This Certificate is valid until:	2022-09-21

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜVRheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle

Date 2020-03-02

Dipl.-Ing. I. Munkler

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60142378 0001
Report No.: 17061663 006

Organization:
Vapo Healthcare Co., Ltd.
Southern unit of third floor
building B
No. 99 Yudai West Rd
High tech district
KunShan, Suzhou
215301 Jiangsu
P.R. China

Scope:

Site included:

Vapo Heathcare Co., Ltd.
Room 1308, Industry Technology Institution,
1699 Zuchongzhi South BLVD,
Kunshan, Jiangsu Province, China

Activities:
Distribution of Nebulizers, Medicine Chamber Spacers,
Infrared Forehead Thermometers

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Date: 2020-03-02

Dipl.-Ing. I. Munkler

HYGISUN

Headquarter: Suite 1308, Industry Technology Institution,
1699 Zuchongzhi South BLVD, KunShan, Suzhou,
Jiangsu Province,P.R.China

EU-KONFORMITÄTSERKLÄRUNG

Diese Konformitätserklärung wurde unter der alleinigen Verantwortung des Herstellers

VAPO HealthCare CO., Ltd.

Southern Unit of the Third Floor Building B, No. 90 Yu Dai West Rd, High Tech District, Kunshan, Suzhou, Jiangsu Province, China

ausgestellt.

EG-Vertreter: Sunbeam International GmbH, Schumanstr.12, Würselen 52146 Deutschland

Hiermit wird erklärt, dass die folgende persönliche Schutzausrüstung (PSA)

Produktbeschreibung: HYGISUN kontaktlose IR Thermometer

Produktmodell (e): VP-T1

den Bestimmungen der folgenden europäischen Verordnung entspricht:

PSA-Verordnung (Persönliche Schutzausrüstung)

Das Modell entspricht den Bestimmungen der Verordnung (EU):

Directive 93/42/EEC Annex II, excluding Section 4

und ist identisch mit der TÜV Rheinland Directive 93/42/EEC Annex II, excluding Section 4, auf die auf der Zertifikatsnummer verwiesen wird:

Zertifikat Nr.: CE DD 60148976 0001 (Ausstellungsdatum: 24/08/2020)

TÜV Rheinland LGA Products GmbH
Tillystraße 2
90431 Nürnberg
Deutschland
CE 0197

Kunshan, China, 01.09.2020

Ming Lu
(Nachname Name)
Qualitätsmanager
VAPO HealthCare CO., Ltd.

苏州雾联医疗科技有限公司
VAPO Healthcare Co.,Ltd.