Declaration of Conformity

Manufacture	NINGBO HAISHU LIFE MEDICAL TECHNOLOGY CO., LTD
Address	NO. 1 JINGHUI ROAD, HENJIE TOWN, HAISHU, NINGBO, ZHEJIANG, CHINA 315181
European Representative	Caretechion GmbH Niederrheinstr 71, 40474 Duesseldorf, Germany United
Product Category	Pressure Steam Sterilizer
Models	LFSS08AA, LFSS12AA, LFSS18AA, LFSS23AA LFSS08AB, LFSS12AB, LFSS18AB, LFSS23AB LFSS08AD, LFSS12AD, LFSS18AD, LFSS23AD LFSS03AA, LFSS08AC

Classification IIb based on MDD 93/42/EEC annex IX rule15

The GMDN code 38671

Conformity Assessment Route Annex II.3

We declare the compliance of the above medical device with the applicable requirements of Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC.

All the supporting documents and files are retained under the premises of the manufactures.

The manufacturer is fully responsible for all of this Declaration.

Notified Body： TÜV SÜD Product Service GmbH,Ridlestrasse. 65,80339 München, Germany.

Identification number：0123

Certificate: G1 002894 0002 Rev.01

Expire date of the Certificate:2023-03-26

Start of CE-Marking：2018-03-27

Place, Date of Issue: Ningbo, 2020.02.20

Signature: _____ （Invalid without stamp）

Name: Lihui Lu

Position： General manager

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT
TÜV SÜD

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 002894 0002 Rev. 01

Manufacturer:

Ningbo Haishu Life Medical Technology Co., Ltd.
No.1 Jinghui Road, Hengjie Town
315181 Haishu, Ningbo, Zhejiang
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

Ningbo Haishu Life Medical Technology Co., Ltd.
No.1 Jinghui Road, Hengjie Town, 315181 Haishu, Ningbo, Zhejiang, PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): Pressure Steam Sterilizer

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.:	SH201158CN01
Valid from:	2020-02-25
Valid until:	2023-03-26

Date, 2020-02-25

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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A4 / 07.17

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

CERTIFICATE

No. Q5 18 01 02894 001

Holder of Certificate: **Ningbo Haishu Life Medical Technology Co., Ltd.**
No.1 Jinghui Road, Hengjie Town
315181 Haishu, Ningbo, Zhejiang
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Ningbo Haishu Life Medical Technology Co., Ltd.
No.1 Jinghui Road, Hengjie Town, 315181
Haishu, Ningbo, Zhejiang, PEOPLE'S
REPUBLIC OF CHINA

Certification Mark:

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

Scope of Certificate: **Design and Development, Production and Distribution of Pressure Steam Sterilizer**

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH17115801

Valid from: 2018-03-27
Valid until: 2021-03-26

04052768654267

Date, 2018-03-27

Stefan Preiß

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

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