

EU Declaration of Conformity

Manufacturer	NINGBO HAISHU LIFE MEDICAL TECHNOLOGY CO., LTD
SRN Number:	CN-MF-000018877
Address	NO.1, JINGHUI ROAD, HENGJIE TOWN, HAISHU, NINGBO, ZHEJIANG, CHINA 315181
European Representative	Caretechion GmbH Niederrheinstr 71, 40474 Duesseldorf, Germany
Product Category	Pressure Steam Sterilizer
Models	LFSS23AA, LFSS18AA, LFSS12AA, LFSS08AA, LFSS23AB, LFSS18AB, LFSS12AB, LFSS08AB, LFSS08AC, LFSS23AD, LFSS18AD, LFSS12AD, LFSS08AD, LFSS03AA
Classification	IIb based on MDD 93/42/EEC annex IX rule15
The GMDN code	38671

Conformity Assessment Route Annex II.3

We declare that the compliance of the above medical devices 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.

We declare that we meet the conditions to continue placing the above items on the market and putting into service until the date of **Dec 31st, 2028**.

The manufacturer is fully responsible for all this Declaration.

Notified Body:	TÜV SÜD Product Service GmbH. Ridlestrasse 65, 80339 Munich, Germany.
Identification number:	0123
CE Certificate No.:	G1 002894 0002 Rev.01
Start date of CE-Marking:	2020-02-25
Expire date of the Certificate:	2023-03-26
Confirmation letter No.:	CL 002894 0003 Rev. 00
Signature:	 (Invalid without stamp)
Name:	Lihui Lu
Position:	General manager
Place, Date of Issue:	Ningbo, 2023-08-01

