

EC Declaration of Conformity

Manufacturer:

Ningbo Ican Machines Co., Ltd.
No.77,Yunlin East Road, Gulin Town, Haishu
District, Ningbo, China

*whose single Authorized
Representative:*

Icanclave Europe, S.L.
Juan Ramon Jimenez 6,
Quart de Poblet, Valencia, Spain

We, the manufacturer, herewith declare that the products

Steam Sterilizers

GMDNS-Code: [P38671]

Model: STE-8-C, STE-12-C, STE-16-C, STE-18-C, STE-23-C, STE-8-D, STE-12-D, STE-18-D, STE-23-D, STE-8-D PRO, STE-12-D PRO, STE-18-D PRO, STE-23-D PRO, STE-18-T, STE-23-T, STE-29-D, STE-29-T, STE-45-T meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class IIb according to Annex IX of the Directive 93/42/EEC. It bears the mark



The product concerned has been designed and manufactured under a quality management system according to Annex II of Directive 93/42/EEC.

Compliance of the designated product with the Directive 93/42/EEC has been assessed and certified by the Notified Body

TÜV Rheinland LGA Products GmbH Tillystraße 2 - 90431 Nürnberg

Certificate No.: HD 60123966 0001

Issue date: 2017-10-26

Expiry date: 2022-10-25

following the procedure relating to the EC Declaration of Conformity set out in Annex II of Directive 93/42/EEC.

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

Reference to the relevant harmonized standards used or references to the other technical specification in the relation to which conformity is declared:

EN 61010-1, EN 61010-2-040, EN 61326-1, EN ISO 14971, EN 13060

According to the Regulation(EU) 2023/607 as regards the transitional provisions for devices certificates issued by notified bodies in accordance with Directive 93/42/EEC that were still valid on 26 May 2021 and that have not been withdrawn afterwards shall remain valid after the end of the period indicated on the certificate until the date 31.12.2028.and we have a written agreement with a notified body for new CE regarding MDR.

We hereby declares that fulfills the conditions necessary for certificate extension according to the REGULATION(EU)2023/607.

EC Declaration of Conformity
TF-STE-DOC Rev.:5

The above mentioned declaration of conformity is exclusively under the responsibility of
Ningbo ican machines Co., Ltd.
No.77, Yunlin East Road, Gulin Town, Haishu District, Ningbo, China

Ningbo 28/11/2023

Place , date



Lin Hui Management Representative