

EU DECLARATION OF CONFORMITY

According to Art. 19, Annex IV of Regulation (EU) 2017/745 on Medical Devices

Manufacturer: Ningbo Ican Machines Co., Ltd.

Address: No.77 Yunlin East Road, Gulin Town,Haishu District,315176 Ningbo,China.

Trademark: icanclave

Product Name: Steam Sterilizer

Model STE-8-D,STE-12-D,STE-18-D,STE-23-D,STE-29-D,STE-3-F,STE-18-T,STE-23-T,
STE-29-D,STE-29-T,STE-45-T,STE-8-D Pro, STE-12-D Pro, STE-18-D Pro,
STE-23-D Pro, STE-18-T Pro,STE-23-T Pro,STE-29-T Pro, STE-45-T Pro

SRN: CN-MF-000024175

European Representative: Icanclave Europe, S.L.
Avenida Juan Ramon Jimenez, 6 46930 Quart de Poblet, Valencia, Spain

SRN: ES-AR-000018282

EMDN code: S9099

Basic UDI-DI: 697261510STES4

Classification acc. to MDR Ax. VIII: Class IIa , rule 16 of MDR Annex VIII

Conformity Assessment Procedure: Annex IX, MDR (2017/745)

CE Certificate No.: M.2024.MDR.1039

Name and ID of the Notified Body: UDEM Adriatic d.o.o.
Address: Radnička cesta 54/R3 Zagreb, Croatia
Number: 2696
Issue date: 28/05/2024 Expiry date: 27/05/2029

We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2017/745 on Medical Devices (MDR). All supporting documentations are retained under the premises of the manufacturer.

Place: Ningbo

Position/Name/Date:



Management Representative/Lin Hui/15.10.2024

Appendix

Model	UDI-DI CODE	Model	UDI-DI CODE
STE-8-D	06972615105095	STE-8-D PRO	06972615105736
STE-12-D	06972615105132	STE-12-D PRO	06972615105743
STE-18-D	06972615105163	STE-18-D PRO	06972615105620
STE-23-D	06972615105217	STE-23-D PRO	06972615105637
STE-18-T	06972615105675	STE-23-T	06972615105682