

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: 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

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 29.05.2024