EU Quality Management System Certificate

Medical Devices Regulation (EU) 2017/745 Annex IX
Chapter I and III (Class IIa, IIb and III Devices)

Certificate Number: M.2024.MDR.1039

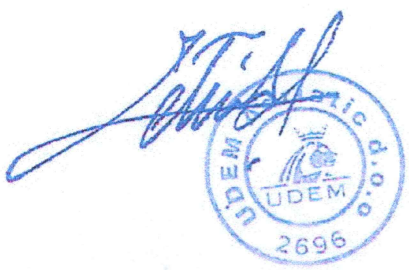
Manufacturer Name	: Ningbo Ican Machines Co., Ltd.
Manufacturer Address	: No. 77 Yunlin East Road, Gulin Town, Haishu District, 315176, Ningbo, China
Single registration number-SRN	: CN-MF-000024175
Authorised Representative Name ***(If applicable)***	: Icanclave Europe S.L.
Authorised Representative Address	: Avenida Juan Ramon Jimenez, 6 46930 Quart de Poblet, Valencia, Spain
Product Scope	: See the product list on the following page(s).

Based on the conformity assessment for the abovementioned manufacturer's quality management system in accordance with (EU) 2017/745 Medical Devices Regulation Annex IX Chapter I and Chapter III, UDEM Adriatic d.o.o. hereby declares that the requirements of Annex IX (Chapter I and Chapter III) of the Regulation (EU) 2017/745 have been met for the listed products in this certificate.
The manufacturer has established, documented and implemented a quality management system, which is subject to periodic surveillance assessments by UDEM Adriatic d.o.o. according to Annex IX Chapter I Section 3 of the aforementioned Regulation.
The report referenced below summarizes the result of assessments/examinations and includes reference to relevant CS, harmonized standards and test reports.
For Class III and Class IIb implantable devices referred to in the second subparagraph of Article 52(4) of Regulation (EU) 2017/745, covered by this certificate, an EU Technical Documentation Assessment Certificate is required before placing them on the market.

Report Number	: MDR.1332
Date of Issue	: 28/05/2024
Recertification Date	:
Reissue Date/No	:
Date of Expiry	: 27/05/2029

If any, Previous Certificate(s) No: NA

UDEM Adriatic d.o.o.
General Manager



UDEM Adriatic d.o.o. is a Notified Body (identification no 2696) under (EU) 2017/745 Medical Devices Regulation.

Address: Radnička cesta 54/ R3 Zagreb– Croatia
E-Mail: info@udemadriatic.com **Web:** www.udemadriatic.com

EU DECLARATION OF CONFORMITY

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

Manufacturer:	Ningbo Ican Machines Co., Ltd.
Trademark:	icanclave
Product Name:	Steam Sterilizer
Model	STE-8-D, STE-12-D, STE-18-D, STE-23-D, STE-29-D 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: Lin Hui

Management Representative

29.05.2024

UDEM Adriatic d.o.o.
Radnička cesta 54/R3
10000 Zagreb, CROATIA

2023/06/15

NINGBO ICAN MACHINES CO.,LTD.
No. 77 Yunlin East Road,
Gulin Town, Haishu District,
315176, Ningbo, China

NOTIFIED BODY CONFIRMATION LETTER

Reference: 2023.MDR.1332.NBCL.0009

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

This letter confirms that, UDEM ADRIATIC D.O.O., a Notified Body (NB) designated under Regulation (EU) 2017/745 (MDR) and identified by the number 2696 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR (on the date of 2021/12/13) and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR (on the date of 2021/12/13) with the following manufacturer:

NINGBO ICAN MACHINES CO.,LTD.
No. 77 Yunlin East Road,
Gulin Town, Haishu District,
315176, Ningbo, China
SRN Number (if available): CN-MF-000024175

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which UDEM Adriatic d.o.o. is also responsible for appropriate surveillance of the corresponding devices under Directive 93/42/EEC (MDD). Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but UDEM Adriatic d.o.o. has not yet taken the responsibility for appropriate surveillance of the corresponding devices under MDD.

UDEM Adriatic d.o.o.
UDEM OIB:50373079764
Radnička cesta 54/R3, Green Gold Centar,IV.kat,Zagreb
Tel:(1)4819601 Fax:(1)4819434
www.udemadriatic.com

In the case of devices covered by certificates issued under MDD that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 March 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120(3c) of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of UDEM Adriatic d.o.o.

Zekeriya AYTAÇ

General Manager

UDEM Adriatic d.o.o.
UDEM OIB:50373079784
Radnička cesta 54/R3, Green Gold Centar,IV.kat,Zagreb
Tel:(1)4819601 Fax: (1)4819434
www.udemadriatic.com

Table 1: Devices covered by this letter and for which UDEM Adriatic d.o.o. is also responsible for appropriate surveillance of the corresponding devices under Directive 93/42/EEC (MDD)

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Table 2: Devices covered by this letter and for which UDEM Adriatic d.o.o. is <u>NOT</u> responsible for appropriate surveillance of the corresponding devices under Directive 93/42/EEC (MDD)

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Steam Sterilizer	Class IIa	N/A	**<u>Certificate 1:</u>** Full Quality Assurance System Certificate No: HD 60123966 0001 TÜV Rheinland LGA Products GmbH (0197)

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2023/06/15	2023.MDR.1332.NBCL.0009	Initial issue

UDEM Adriatic d.o.o.
UDEM OIB:50373079784
Radnička cesta 54/R3, Green Gold Centar,IV.kat,Zagreb
Tel:(1)4819601 Fax:(1)4819434
www.udemadriatic.com