

# 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

**UDEM Adriatic d.o.o.**  
**General Manager**

**If any, Previous Certificate(s) No:** NA

**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](http://www.udemadriatic.com)

# 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

## PRODUCT LIST COVERED BY THE CERTIFICATE

PRODUCT NAME	BASIC UDI-DI	RISK CLASS	EMDN CODE	MODEL	TYPE	INTENDED PURPOSE
icanCLAVE Steam Sterilizer	697261510STES4	IIa	S9099	STE-23-D	NA	The device designed for total elimination and/or inactivation of microorganisms from medical devices and related products, placed in sterilization wraps/packageing, using pressurized steam as the sterilizing agent. It is used for products non-sensitive to high temperature, water, or steam.
				STE-18-D		
				STE-12-D		
				STE-8-D		

Conditions for or limitations to the validity of this certificate : none

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](mailto:info@udemadriatic.com) Web: [www.udemadriatic.com](http://www.udemadriatic.com)



# 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

CERTIFICATE HISTORY		
Rev. No.	Rev. Date	Description of Revision
00	28/05/2024	Initial Certification



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](mailto:info@udemadriatic.com) Web: [www.udemadriatic.com](http://www.udemadriatic.com)