

# Certificate

CISQ / RINA has issued an IQNET recognized certificate that the organization:

## **PRESVAC S.R.L.**

**CALLE 34 (FRANCIA) 3917 1650 San Martin (BA) ARGENTINA**

has implemented and maintains a/an

### **Medical Devices - Quality Management System**

for the following scope:

**DESIGN, DEVELOPMENT, PRODUCTION AND TECHNICAL ASSISTANCE OF TABLE TOP CENTRIFUGES, REFRIGERATED CENTRIFUGES, AGITATORS, ACCESSORIES AND COLD SYSTEMS FOR BLOOD BANKS AND LABORATORIES**

which fulfills the requirements of the following standard:

### **ISO 13485:2016**

Issued on: **2024-09-20**

First Issued on: **2015-07-03**

Expires on: **2027-07-02**

All details about any legal entities, operative units and related activities included in this certificate are contained in CISQ/RINA original certificate no.: **DM/15/122/S**

Registration Number: **IT-101696**



**Alex Stoichitoiu**  
President of IQNET



**Mario Romersi**  
President of CISQ



This attestation is directly linked to the IQNET Member's original certificate and shall not be used as a stand-alone document.

**IQNET Members\*:**

**AENOR** Spain **AFNOR Certification** France **APCER** Portugal **CCC** Cyprus **CISQ** Italy **CQC** China **CQM** China **CQS** Czech Republic  
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Colombia **ICS** Bosnia and Herzegovina **INTECO** Costa Rica **IRAM** Argentina **JQA** Japan **KFQ** Korea **LSQA** Uruguay **MIRTEC** Greece  
**MSZT** Hungary **Nemko AS** Norway **NSAI** Ireland **NYCE-SIGE** México **PCBC** Poland **Quality Austria** Austria **SII** Israel **SIQ** Slovenia  
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\* The list of IQNET Members is valid at the time of issue of this certificate. Updated information is available under [www.iqnet-certification.com](http://www.iqnet-certification.com)



CISQ is a member of



The International Certification Network  
www.iqnet-certification.com

**CERTIFICADO N°**  
**CERTIFICATE No.**

**DM/15/122/S**

SE CERTIFICA QUE EL SISTEMA DE GESTIÓN DE CALIDAD DE  
*IT IS HEREBY CERTIFIED THAT THE QUALITY MANAGEMENT SYSTEM OF*

**PRESVAC S.R.L.**

CALLE 34 (FRANCIA) 3917 1650 San Martin (BA) ARGENTINA

EN LAS SIGUIENTES UNIDADES OPERATIVAS / *IN THE FOLLOWING OPERATIONAL UNITS*

CALLE 34 (FRANCIA) 3917 1650 San Martin (BA) ARGENTINA

CUMPLE CON LA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

**ISO 13485:2016**

El certificado traslada la actualización regulatoria relativa a la norma EN ISO 13485:2021 aplicable en el Área Económica Europea  
*The certificate transposes the regulatory update relating to the EN ISO 13485:2021 standard applicable in the European Economic Area*

PARA EL SIGUIENTE CAMPO DE ACTIVIDADES / *FOR THE FOLLOWING FIELD(S) OF ACTIVITIES*

DISEÑO, DESARROLLO, PRODUCCIÓN Y ASISTENCIA TÉCNICA DE CENTRÍFUGAS DE MESA, CENTRIFUGAS REFRIGERADAS, AGITADORES, ACCESORIOS Y SISTEMAS DE FRIO PARA BANCOS DE SANGRE Y LABORATORIOS

*DESIGN, DEVELOPMENT, PRODUCTION AND TECHNICAL ASSISTANCE OF TABLE TOP CENTRIFUGES, REFRIGERATED CENTRIFUGES, AGITATORS, ACCESSORIES AND COLD SYSTEMS FOR BLOOD BANKS AND LABORATORIES*

Para detalles referentes a excepciones a los requerimientos de la Norma, se deberá consultar el Manual de Calidad  
*Reference is to be made to the Quality Manual for details regarding the exemptions from the requirements of the standard*

El uso y validez de este certificado está sujeto al cumplimiento de los documentos RINA: Reglamento para la Certificación de Sistemas de Gestión de Calidad en el sector de los productos sanitarios  
*The use and validity of this certificate are subject to compliance with the RINA document: Rules for the certification of Quality Management Systems in the Medical Devices sector*

La validez de este certificado depende de las auditorias semestrales / anuales y revisión completa cada tres años del Sistema de Gestión  
*The validity of this certificate is dependent on an annual / six monthly audit and on a complete review, every three years, of the management system*

Primera emisión <i>First Issue</i>	<u>03.07.2015</u>	Fecha de renovación de la decisión <i>Renewal decision date</i>	<u>20.09.2024</u>
Fecha de vencimiento <i>Expiry Date</i>	<u>02.07.2027</u>	Fecha de revisión <i>Revision date</i>	<u>20.09.2024</u>

Fecha de vencimiento del ciclo previo de certificación el 02/07/2024 y auditoría de renovación finalizada el 23/08/2024  
*Previous certification cycle expiry date 02/07/2024 and renewal audit ended on 23/08/2024*

Lucia Nunes Pereira

Latin America Certification Area, Head

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www.cisq.com

CISQ es la Federación Italiana de Entes de Certificación del Sistema de Gestión

*CISQ is the Italian Federation of management system Certification Bodies*



SGQ N° 002 A

Signatory of EA, IAF and ILAC Mutual Recognition Agreements