

AENOR

Confía



Certificado de Sistema de Gestión de la Calidad de Productos Sanitarios



GS-0004/2016

AENOR certifica que la organización

VITRO, S.A.

dispone de un sistema de gestión de la calidad de productos sanitarios conforme con la Norma UNE-EN ISO 13485:2018

para las actividades: A) Diseño, desarrollo, fabricación de instrumentos de diagnóstico in vitro para la detección y diagnóstico de enfermedades infecciosas y tumorales mediante PCR e hibridación reversa sobre membrana.
B) Diseño, desarrollo, producción y comercialización de anticuerpos, kits de detección para inmunohistoquímica e hibridación in situ, sistemas de diagnóstico molecular, tinciones y reactivos IVD para laboratorios clínicos.

que se realiza/n en: Direcciones indicadas en el Anexo

Fecha de primera emisión: 2016-04-18
Fecha de última emisión: 2022-04-18
Fecha de expiración: 2025-04-18



Rafael GARCÍA MEIRO
Director General



THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

AENOR has issued an IQNet recognized certificate that the organization:

VITRO, S.A.

SEE ADDRESSES SPECIFIED IN ANNEX

has implemented and maintains a

Medical devices – Quality Management Systems

for the following scope:

A) Design, development, manufacturing of in vitro diagnostic instruments for the detection of both DNA and Protein molecular targets based on microarray technology into porous membranes by flow-through.

B) Design, development, manufacture and sales of antibodies, detection kits for immunohistochemistry and in situ hybridization, molecular diagnostic systems, staining solutions and IVD reagents for clinical laboratories.

which fulfills the requirements of the following standard

ISO 13485:2016

First issued on: **2016-04-18** Last issued: **2022-04-18** Validity date: **2025-04-18**

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

Registration Number: ES-GS-0004/2016

AENOR
Confia



Alex Stoichitoiu
President of IQNet

Rafael GARCÍA MEIRO
Chief Executive Officer

IQNet Partners*:

AENOR Spain AFNOR Certification France APCER Portugal CCC Cyprus CISQ Italy
CQC China CQM China CQS Czech Republic Cro Cert Croatia DQS Holding GmbH Germany EAGLE Certification Group USA
FCAV Brazil FONDONORMA Venezuela ICONTEC Colombia Inspecta Sertifiointi Oy Finland INTECO Costa Rica
IRAM Argentina JQA Japan KFQ Korea MIRTEC Greece MSZT Hungary Nemko AS Norway NSAI Ireland
NYCE-SIGE México PCBC Poland Quality Austria Austria RR Russia SII Israel SIQ Slovenia
SIRIM QAS International Malaysia SQS Switzerland SRAC Romania TEST St Petersburg Russia TSE Turkey YUQS Serbia

* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com



THE INTERNATIONAL CERTIFICATION NETWORK

Annex to IQNet Certificate Number ES-GS-0004/2016
VITRO, S.A.

(A y B) SEDE CENTRAL:
 LUIS FUENTES BEJARANO, 60
 41020 - SEVILLA

(A) SEDE ALCALÁ DE GUADAIRA:
 CL SAN NICOLÁS, 103-105
 41500 - ALCALÁ DE GUADAIRA
 (SEVILLA)

(B) SEDE GRANADA:
 PQ TECNOLÓGICO CIENCIAS DE LA SALUD. AV. DEL CONOCIMIENTO , 100
 18016 - GRANADA

First issued on: **2016-04-18** Last issued: **2022-04-18** Validity date: **2025-04-18**

This annex is only valid in connection with the above-mentioned certificate.



Alex Stoichitoiu
 President of IQNet

Rafael GARCÍA MEIRO
 Chief Executive Officer

AENOR
 Confía

IQNet Partners*:

AENOR Spain AFNOR Certification France APCER Portugal CCC Cyprus CISQ Italy CQC China CQM China CQS Czech Republic
 Cro Cert Croatia DQS Holding GmbH Germany FCAV Brazil FONDONORMA Venezuela ICONTEC Colombia Inspecta Sertifiointi
 Oy Finland INTECO Costa Rica IRAM Argentina JQA Japan KFQ Korea MIRTEC Greece MSZT Hungary Nemko AS Norway
 NSAI Ireland NYCE-SIGE México PCBC Poland Quality Austria Austria RR Russia SII Israel SIQ Slovenia
 SIRIM QAS International Malaysia SQS Switzerland SRAC Romania TEST St Petersburg Russia TSE Turkey YUQS Serbia
 IQNet is represented in the USA by: AFNOR Certification, CISQ, DQS Holding GmbH and NSAI Inc.

* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com