



THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

**IQNet and
SRAC**

hereby certify that the organization

DIAMEDIX IMPEX S.A.

Str. Fabrica de Glucoză, nr. 15A, clădirea A4, sector 2, București

for the following field of activities

Import, storage, trade medical devices for vitro diagnostic (IVD): Reagents and reagent products, calibrators and control materials for: Clinical Chemistry, Immunochemistry (Immunology), Hematology / Hemostasis/Imunohematology, Microbiology, Infectious Immunology, Histology / Cytology, Genetics testing. Import, storage, trade, mounting and service of in vitro diagnostic instruments and software; IVD medical devices other than those specified above

has implemented and maintains a

Quality Management System

which fulfils the requirements of the following standard

EN ISO 13485 : 2012

Issued on : 2016 - 03 - 17

Validity date : 2019 - 03 - 16

Registration Number : RO - 0083



Michael Drechsel
President of IQNet

ing. Mihaela Cristea
SRAC General Manager



IQNet Partners*:

AENOR Spain AFNOR Certification France AIB-Vinçotte International Belgium 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 IMNC Mexico Inspecta Certification Finland INTECO Costa Rica
IRAM Argentina JQA Japan KFQ Korea MIRTEC Greece MSZT Hungary Nemko AS Norway NSAI Ireland PCBC Poland
Quality Austria Austria RR Russia SIGE Mexico 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

acreditat pentru
CERTIFICARE



SR EN ISO/CEI 17021:2011
CERTIFICAT DE ACREDITARE
SM 004



C E R T I F I C A T

SRAC certifică organizația/ certifies the organisation

DIAMEDIX IMPEX S.A.

Str. Fabrica de Glucoză, nr. 15A, clădirea A4, sector 2, București

**pentru următoarele activități/
for the following fields of activities**

Import, depozitare, comercializare dispozitive medicale de diagnostic in vitro (IVD): Reactivi și produse reactive, calibranți și materiale de control pentru: Chimie Clinică, Imunochimie (Imunologie), Hematologie/Hemostază/Imunohematologie, Microbiologie, Imunologie Infecțioasă, Histologie/Citologie, Testare Genetică. Import, depozitare, comercializare, montare și service instrumente de diagnostic in vitro și software; dispozitive medicale IVD, altele decât cele specificate anterior

Import, storage, trade medical devices for vitro diagnostic (IVD): Reagents and reagent products, calibrators and control materials for: Clinical Chemistry, Immunochemistry (Immunology) Hematology / Hemostasis/Imunohematology, Microbiology, Infectious Immunology, Histology / Cytology, Genetics testing. Import, storage, trade, mounting and service of in vitro diagnostic instruments and software; IVD medical devices other than those specified above

că are implementat și menține un
sistem de managementul calității
conform condițiilor din standardul

which has implemented and maintains a
quality management system
which fulfils the requirements of the standard

SR EN ISO 13485:2012 (EN ISO 13485:2012)



Valabilitatea certificatului este condiționată de
efectuarea supravegheților anuale până la data de:



03-
2017

03-
2018

nr. certificat/ certificate registration no. **83**

data inițială a certificării/ initial certification date **17 martie 2016**

data recertificării/ reissuing date -

data ultimei actualizări/ last update -

valabil până la/ valid until **16 martie 2019** (cu condiția vizării anuale)

SRAC CERT SRL, Str. Vasile Pârvan Nr. 14, Sector 1, București www.srac.ro

Director General
Ing. Mihaela Cristea