

CERTIFICATO n°
CERTIFICATE n° **7853**

*IQNet, the association of the world's first class certification bodies, is the largest provider of management System Certification in the world.
IQNet is composed of more than 30 bodies and counts over 150 subsidiaries all over the globe.*

SI CERTIFICA CHE L'ORGANIZZAZIONE
WE HEREBY CERTIFY THAT THE ORGANIZATION

ROCHE DIAGNOSTICS S.P.A.

IT-20900 MONZA (MB) - VIALE GIAN BATTISTA STUCCHI, 110

NELLE SEGUENTI UNITA' OPERATIVE / IN THE FOLLOWING OPERATIVE UNITS

IT - 20900 MONZA (MB) - VIALE GIAN BATTISTA STUCCHI, 110

HA ATTUATO E MANTIENE UN SISTEMA DI GESTIONE QUALITA' CHE E' CONFORME ALLA NORMA
HAS IMPLEMENTED AND MAINTAINS A QUALITY MANAGEMENT SYSTEM WHICH COMPLIES WITH THE FOLLOWING STANDARD

UNI CEI EN ISO 13485:2016

PER LE SEGUENTI ATTIVITÀ / FOR THE FOLLOWING ACTIVITIES

Commercializzazione e distribuzione di diagnostici in vitro e dispositivi medici.
Attività di supporto pre e post-vendita e servizi di assistenza al cliente.
Sviluppo e definizione di flussi operativi e di soluzioni organizzative per i laboratori di analisi.

*Marketing, sales and distribution of products in vitro diagnostics and medical devices.
Pre and post-sales support activities and customer care services.
Development and definition of operating flows and organizational solutions for laboratories of analysis.*

IL PRESENTE CERTIFICATO È SOGGETTO AL RISPETTO DEL REGOLAMENTO PER LA CERTIFICAZIONE DEI SISTEMI DI GESTIONE
THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE REQUIREMENTS OF THE RULES FOR THE CERTIFICATION OF MANAGEMENT S SYSTEMS

PRIMA EMISSIONE FIRST ISSUE	18/03/1997
DATA DELIBERA DECISION DATE	18/05/2022
DATA SCADENZA EXPIRY DATE	23/05/2025
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CERTIQUALITY S.r.l. IL PRESIDENTE
Via G. Giardino 4 - 20123 MILANO (MI) - ITALY



SGQ n. 008 A

Membro degli Accordi di Mutuo riconoscimento EA, IAF e ILAC.
Signatory of EA, IAF and ILAC Mutual Recognition Agreements.



www.cisq.com

CISQ è la Federazione Italiana di Organismi di Certificazione dei sistemi di gestione aziendale.
CISQ is the Italian Federation of management system Certification Bodies.



THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

CISQ/CERTIQUALITY S.r.l.

has issued an IQNet recognised certificate that the organization:

ROCHE DIAGNOSTICS S.P.A.

IT-20900 MONZA (MB) - VIALE GIAN BATTISTA STUCCHI 110

for the following scope

Marketing, sales and distribution of products in vitro diagnostics and medical devices. Pre and post-sales support activities and customer care services. Development and definition of operating flows and organizational solutions for laboratories of analysis.

has implemented and maintains a
Quality Management System
which fulfills the requirements of the following standard
ISO 13485:2016

Issued on: 18/05/2022
First issued on: 18/03/1997
Expires on: 23/05/2025

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

Registration number: IT- 33226

Cisq Certificate: 7853



Alex Stoichitoiu
President of IQNET



Ing. Mario Romersi
President of CISQ

IQNet Partners*:

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