



CERTIFICATO n. **7853**
 CERTIFICATE No

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 G. B. 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 ATTIVITA' / FOR THE FOLLOWING ACTIVITIES

Commercializzazione e distribuzione di prodotti per la ricerca, 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 for research, 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 E' 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 SYSTEMS

PRIMA EMISSIONE **18/03/1997**
 FIRST ISSUE
 DATA DELIBERA **16/05/2019**
 DECISION DATE
 DATA SCADENZA **24/05/2022**
 EXPIRY DATE
 EMISSIONE CORRENTE **16/05/2019**
 ISSUE DATE

CERTIQUALITY S.r.l. - IL PRESIDENTE
 Via G. Giardino 4 - 20123 MILANO (MI) - ITALY



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.

For information concerning the validity of the certificate, you can visit the site www.certiquality.it

The validity this certificate depends on annual audit and on a complete review every three years of the Management System.



SGQ n. 003 A SSI N. 007 G
 SGA n. 001 D SIGE N. 001 M
 SCH n. 002 F ISP N. 006 O
 FSM n. 006 I EMAS N. 008 P
 PRS n. 003 B ITX N. 004 L
 DAP n. 003 H
 PRS n. 100 C

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 for research, 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: **2019-05-16**

First issued on: **1997-03-18**

Expires on: **2022-05-24**

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**



Alex Stoichitoiu
President of IQNET



Ing. Claudio Provetti
President of CISQ

IQNet Partners*:

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