



CERTIFICATO n. **22990**  
CERTIFICATE No

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

# ROCHE DIABETES CARE ITALY SPA

*For information concerning the validity of the certificate, you can visit the site [www.certiquality.it](http://www.certiquality.it)*

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

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 EN ISO 9001:2015

PER LE SEGUENTI ATTIVITA' / FOR THE FOLLOWING ACTIVITIES **SETTORE** **IAF 29**  
**CODE**

**Commercializzazione e distribuzione di sistemi diagnostici in vitro, dispositivi medici, dispositivi impiantabili attivi, servizi integrati Health Care e servizi dedicati al paziente per la gestione del diabete. Attività di supporto pre e post-vendita e servizi di assistenza al Cliente.**

**Marketing and distribution of in vitro diagnostic systems, medical devices, active implantable devices, integrated Health Care services and patient services for diabetes management. Pre and post-sales support activities and customer assistance services.**

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 **06/06/2013**  
FIRST ISSUE  
DATA DELIBERA **28/05/2019**  
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DATA SCADENZA **29/05/2022**  
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ISSUE DATE

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



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SGA F 001 D 88 N 001 M  
SCR F 002 F 88 N 006 O  
FSM F 006 I EIA/AS N 008 P  
PRO F 008 B ITA N 004 L  
CAP F 003 H  
PRS F 100 C

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THE INTERNATIONAL CERTIFICATION NETWORK

# CERTIFICATE

**CISQ/CERTIQUALITY S.r.l.**

has issued an IQNet recognised certificate that the organization:

## ROCHE DIABETES CARE ITALY SPA

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

for the following scope

Marketing and distribution of in vitro diagnostic systems, medical devices, active implantable devices, integrated Health Care services and patient services for diabetes management. Pre and post-sales support activities and customer assistance services.

has implemented and maintains a  
**Quality Management System**  
which fulfills the requirements of the following standard

**ISO 9001:2015**

Issued on: **2019-05-28**

First issued on: **2013-06-06**

Expires on: **2022-05-29**

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-100265**



*Alex Stoichitoiu*  
**President of IQNET**



*Ing. Claudio Provetti*  
**President of CISQ**

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CERTIFICATO n. **22991**  
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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

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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 sistemi diagnostici in vitro e di dispositivi medici e dispositivi medici impiantabili attivi per la gestione del diabete. Attività di supporto pre-vendita e post-vendita e servizi di assistenza al cliente.

*Marketing, sales and distribution of in vitro diagnostics system, medical devices and active implantable medical devices for diabetes.*

*Pre-sales and post-sales support activities and customer support services.*

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**ROCHE DIABETES CARE ITALY SPA**

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

for the following scope

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**Quality Management System**

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**ISO 13485:2016**

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*Registration number:* **IT-100266**




*Alex Stoichitoiu*  
President of IQNET




*Ing. Claudio Provetti*  
President of CISQ

**IQNet Partners\*:**

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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  
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