



CISQ is a member of



The International Certification Network
www.iqnet-certification.com

CERTIFICATO N. **ICIM-13485-052012-00**
CERTIFICATE No. _____

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITÀ DI
WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

GEMELLI DIGITAL MEDICINE & HEALTH SRL

SEDE CENTRALE / HEADQUARTER

VIA DELLA PINETA SACCHETTI, 502/504 00168 ROMA RM IT - Italia

PER LE UNITÀ OPERATIVE VEDERE L'ALLEGATO
FOR OPERATIVE UNITS SEE ATTACHMENT

È CONFORME ALLA NORMA

UNI CEI EN ISO 13485:2021

IS IN COMPLIANCE WITH THE STANDARD

ISO 13485:2016

Sistema di Gestione per la Qualità / Quality Management System

PER LE SEGUENTI ATTIVITÀ / FOR THE FOLLOWING ACTIVITIES

Erogazione del servizio di gestione della progettazione di piattaforme software medicali e correlati servizi.

Provision of management services for the design of medical software platforms and related services.

Riferirsi alla documentazione del Sistema di Gestione per la Qualità aziendale per l'applicabilità dei requisiti della norma di riferimento.
Refer to the documentation of the Quality Management System for details of application to reference standard requirements.

Il presente certificato è soggetto al rispetto del documento ICIM "Regolamento per la certificazione dei sistemi di gestione" e al relativo Schema specifico.
The use and the validity of this certificate shall satisfy the requirements of the ICIM document "Rules for the certification of company management systems" and specific Scheme.

Per informazioni puntuali e aggiornate circa eventuali variazioni intervenute nello stato della certificazione di cui al presente certificato, si prega di contattare il n° telefonico +39 02 725341 o indirizzo e-mail info@icim.it.

For timely and updated information about any changes in the certification status referred to in this certificate, please contact the number +39 02 725341 or email address info@icim.it.

DATA EMISSIONE
FIRST ISSUE
17/03/2026

EMISSIONE CORRENTE
CURRENT ISSUE
17/03/2026

DATA DI SCADENZA
EXPIRING DATE
16/03/2029

Vincenzo Delacqua
Rappresentante Direzione / Management Representative
ICIM S.p.A.

Piazza Don Enrico Mabelli, 75 – 20099 Sesto San Giovanni (MI)
www.icim.it



00012



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.



CISQ is a member of



The International Certification Network
www.iqnet-certification.com

Allegato al CERTIFICATO N.
Attachment to CERTIFICATE No.

ICIM-13485-052012-00

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITÀ DI
WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

GEMELLI DIGITAL MEDICINE & HEALTH SRL

Comprende oltre la Sede Centrale citata sul Certificato, anche le seguenti Unità Operative:
In addition to the Headquarter mentioned on the Certificate, it also includes the following Operative Units:

VIA DELLA PINETA SACCHETTI,
502/504 00168 ROMA RM IT - Italia

Erogazione del servizio
di gestione della
progettazione di
piattaforme software
medicali e correlati
servizi.

LARGO AGOSTINO GEMELLI, 8
00168 ROMA RM IT - Italia

Sede Legale.



00012



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.

Certificate

CISQ/ICIM S.P.A. has issued an IQNET recognized certificate that the organization:

GEMELLI DIGITAL MEDICINE & HEALTH SRL
VIA DELLA PINETA SACCHETTI, 502/504 00168 ROMA RM IT - Italia

For Operative Units see Annex/Annexes

has implemented and maintains a/an

Quality Management System

for the following scope:

Provision of management services for the design of medical software platforms and related services.

which fulfils the requirements of the following standard:

ISO 13485:2016

Issued on: **2026-03-17**
First issued on: **2026-03-17**
Expires on: **2029-03-16**

Registration Number:
IT-150651 ICIM-13485-052012-00


Alex Stoichitoiu
President of IQNET


Mario Romersi
President of CISQ



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

IQNET Members*:

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 **ICS** Bosnia and Herzegovina **INTECO** Costa Rica **IRAM** Argentina **JQA** Japan **KFQ** Korea **LSQA** Uruguay **MIRTEC** Greece
MSZT Hungary **Nemko AS** Norway **NSAI** Ireland **NYCE-SIGE** Mexico **PCBC** Poland **Quality Austria** Austria **SII** Israel **SIQ** Slovenia
SIRIM QAS International Malaysia **SQS** Switzerland **SRAC** Romania **TSE** Turkey **YUQS** Serbia

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

Annex 1 to IQNET Certificate Number:
IT-150651 ICIM-13485-052012-00

GEMELLI DIGITAL MEDICINE & HEALTH SRL
VIA DELLA PINETA SACCHETTI, 502/504 00168 ROMA RM IT - Italia

List of additional locations:

LARGO AGOSTINO GEMELLI, 8 00168 ROMA RM IT - Italia

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

IQNET Members*:

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 **ICS** Bosnia and Herzegovina **INTECO** Costa Rica **IRAM** Argentina **JQA** Japan **KFQ** Korea **LSQA** Uruguay **MIRTEC** Greece
MSZT Hungary **Nemko AS** Norway **NSAI** Ireland **NYCE-SIGE** México **PCBC** Poland **Quality Austria** Austria **SII** Israel **SIQ** Slovenia
SIRIM QAS International Malaysia **SQS** Switzerland **SRAC** Romania **TSE** Türkiye **YUGS** Serbia

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