



THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

IQNet and its partner
CISQ/CERTIQUALITY S.r.l.
 hereby certify that the organization

BIOSIGMA S.R.L.

I - 30010 CANTARANA DI CONA (VE) - VIA VALLETTA, 6

has implemented and maintains a

Quality Management System

which fulfills the requirements of the following standard

ISO 13485:2003

for the following activities

Code **EA 19**

Design, production and sale of disposable labware items and in vitro diagnostics.
 Sale of medical devices, in vitro diagnostics labware items, glassware and accessories
 for public and private healthcare facilities.

in the following operative units

I - 30010 CANTARANA DI CONA (VE) - VIA VALLETTA, 6

Issued on: **2007-10-31**

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Registration Number: **IT-38353**



René Wasmer

President of IQNET



Gianrenzo Prati

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



ISTITUTO DI CERTIFICAZIONE DELLA QUALITÀ
www.certiquality.it

CERTIFICATO n. **8595**
CERTIFICATE No

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

BIOSIGMA S.R.L.

I - 30010 CANTARANA DI CONA (VE) - VIA VALLETTA, 6

NELLE SEGUENTI UNITA' OPERATIVE / IN THE FOLLOWING OPERATIVE UNITS
I - 30010 CANTARANA DI CONA (VE) - VIA VALLETTA, 6

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

UNI EN ISO 13485:2004

PER LE SEGUENTI ATTIVITÀ / FOR THE FOLLOWING ACTIVITIES SETTORE
CODE **EA 19**

Progettazione, produzione e vendita di articoli monouso da laboratorio e diagnostici in vitro.
Commercializzazione di dispositivi medici, diagnostici in vitro, articoli da laboratorio,
vetreria, accessori per strutture sanitarie pubbliche e private.
Design, production and sale of disposable labware items and in vitro diagnostics.
Sale of medical devices, in vitro diagnostics labware items, glassware and accessories
for public and private healthcare facilities.

Certificazione rilasciata in conformità al Regolamento Tecnico SINCERT RT 20

RIFERIRSI AL MANUALE DI GESTIONE QUALITÀ PER L'APPLICABILITÀ DEI REQUISITI DELLA NORMA
REFER TO MANAGEMENT SYSTEM MANUAL FOR DETAILS OF APPLICATION TO STANDARD REQUIREMENTS

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 SYSTEMS

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

CISQ è la Federazione Italiana di
Organismi di Certificazione dei
sistemi di gestione aziendale

CISQ is the Italian Federation
of management system
Certification Bodies



SGQ N° 008A
SGA N° 001D
SCR N° 002F
PRD N° 008B

Membro degli accordi di mutuo riconoscimento EA IAF
Signatory of EA and IAF mutual recognition agreements

Per informazioni sulla validità del
certificato, visitare il sito
www.certiquality.it

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

La validità del presente certificato è
subordinata a sorveglianza periodica
annuale ed al riesame completo del Sistema
di Gestione con periodicità triennale.

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



www.cisq.com

CISQ is a member of



THE INTERNATIONAL CERTIFICATION NETWORK
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*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.*