

THE INTERNATIONAL CERTIFICATION NETWORK

# CERTIFICATE

IQNet and its partner  
**CISQ/IMQ-CSQ**  
hereby certify that the organization

**BIO-OPTICA MILANO SPA**  
INSTRUMENT DIVISION  
VIA MILANO 6 - 20068 PESCHIERA BORROMEO (MI)  
**BIO-STAIN SRL**  
VIA COLLAMARINI 16/B - 40138 BOLOGNA (BO)

*for the following field of activities*  
*Design, manufacturing, distribution and service of instruments,*  
*consumables and reagents for histocytology's labs*  
*Refer to quality manual for details of applications to ISO 9001:2008 requirements*

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

## ISO 9001:2008

Issued on: 2014 - 07 - 15

Expiry date: 2017 - 07 - 15

*Registration Number:* IT - 65108

The status of validity of the certificate can be verified at <http://www.cisq.com> or by e-mail to [fedcisq@cisq.com](mailto:fedcisq@cisq.com)



Michael Drechsel  
President of IQNET



Ing. Claudio Provetti  
President of CISQ

**IQNet Partners\*:**

AENOR Spain AFNOR Certification France AIB-Vinçotte International Belgium ANCE-SIGE Mexico APCER Portugal CCC Cyprus  
CISQ Italy CQC China CQM China CQS Czech Republic Cro Cert Croatia DQS Holding GmbH Germany  
FCAV Brazil FONDONORMA Venezuela ICONTEC Colombia IMNC Mexico Inspecta Certification Finland IRAM Argentina  
JQA Japan KFQ Korea MIRTEC Greece MSZT Hungary Nemko AS Norway NSAI Ireland 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

IQNet is represented in the USA by: AFNOR Certification, CISQ, DQS Holding GmbH and NSAI Inc.  
\* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under [www.iqnet-certification.com](http://www.iqnet-certification.com)



www.imq.it

CERTIFICATO N. 9124.BMED  
CERTIFICATE N.

SI CERTIFICA CHE IL SISTEMA QUALITA' DI  
WE HEREBY CERTIFY THAT THE QUALITY SYSTEM OPERATED BY

**BIO-OPTICA MILANO SPA**

VIA SAN FAUSTINO 58 - 20134 MILANO (MI)

UNITA' OPERATIVE  
OPERATIVE UNITS

**INSTRUMENT DIVISION**

VIA MILANO 6 - 20068 PESCHIERA BORROMEO (MI)

**BIO-STAIN SRL**

VIA COLLAMARINI 16 - 40138 BOLOGNA (BO)

E' CONFORME ALLA NORMA  
IS IN COMPLIANCE WITH THE STANDARD

**EN ISO 13485:2012**

PER LE SEGUENTI ATTIVITA'  
FOR THE FOLLOWING ACTIVITIES

Progettazione, produzione, distribuzione e assistenza di strumenti,  
materiali di consumo e reagenti per i laboratori di citoistopatologia  
*Design, manufacturing, distribution and service of instruments,  
consumables and reagents for histocytology's labs*

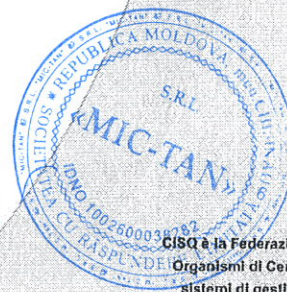
Certificazione rilasciata in conformità al Regolamento Tecnico SINCERT RT -20.

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 CERTIFICATION OF MANAGEMENT SYSTEMS*

DATE:	PRIMA CERTIFICAZIONE FIRST CERTIFICATION	EMISSIONE CORRENTE CURRENT ISSUE	SCADENZA EXPIRY
	2008-09-19	2014-07-15	2017-07-15

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO 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.



EA: 19, 29

SGO N°005A, SGA N°006D, SCR N°005F  
SSI N°003G, FSM N°007I, SGE N°008M  
EMAS N°003P, GHG N°0110, PRD N°005B  
PRS N°009C, ISP N°003E, LAB N°0121  
LAT N°021  
Membro degli Accordi di Riconoscimento EA, UK e ILAC  
Signatory of EA, UK and ILAC Mutual Recognition Agreements

La validità del certificato è subordinata a sorveglianza annuale e riesame completo del Sistema di Gestione con periodicità triennale  
The validity of the certificate is submitted to annual audit and a reassessment of the entire Management System within three years



www.cisq.com

CISQ is a member of



www.iqnet-certification.com

*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.*

To whom it may concern

**REF.: AUTHORIZATION LETTER**

We, company Bio-Optica Milano S.p.A. located in San Faustino str., 58 – 20134 Milano (Italy) - VAT number: 06754140157, as manufacturer of Chemicals, Instruments and Consumables for Pathologic Anatomy field and having facilities in San Faustino str., 58 declares that:

**LTD "MIC-TAN"  
(SRL "MIC-TAN")  
ALEXANDRU CEL BUN, 38  
2001 KISHINEV  
MOLDOVA**

Is authorised to distribute in Moldova the products manufactured and distributed by us for Moldavian market, and it is authorized to take part in tenders on our behalf.

We hereby guarantee the quality and the performance of the offered goods and authorize LTD "MIC-TAN" to assure for the mentioned products the installation services, to bring them into operation, and to provide the maintenance and technical assistance.

This letter is valid till 31.12.2018

Milano, 22.02.2018

**Bio-Optica Milano S.p.a.  
Export Department**

**Bio-Optica Milano S.p.A.**  
20134 MILANO - via S. Faustino, 58  
Tel. 2127131 - Telefax 2153000  
Cod. Fisc. - P. Iva 06754140157



Partita IVA - VAT Number: IT06754140157  
Tribunale di Milano REA n. 1118800 - c.c.i.a.a. di Milano



## Coverglasses

**IVD** In vitro diagnostic – medical device

CND code: W0503900202



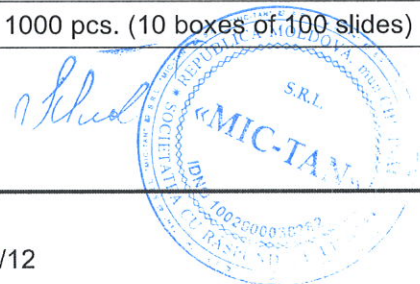
### General features

Cover glasses for microscopy.



Code	Dimension (mm)	Packaging
09-01818	18 x 18	1000 pcs. (5 boxes of 200 slides)
09-01824	18 x 24	1000 pcs. (5 boxes of 200 slides)
09-02020	20 x 20	1000 pcs. (5 boxes of 200 slides)
09-02126	21 x 26	1000 pcs. (10 boxes of 100 slides)
09-02222	22 x 22	1000 pcs. (5 boxes of 200 slides)
09-02232	22 x 32	1000 pcs. (10 boxes of 100 slides)
09-02240	22 x 40	1000 pcs. (10 boxes of 100 slides)
09-02250	22 x 50	1000 pcs. (10 boxes of 100 slides)
09-02424	24 x 24	1000 pcs. (5 boxes of 200 slides)
09-02432	24 x 32	1000 pcs. (10 boxes of 100 slides)
09-02440	24 x 40	1000 pcs. (10 boxes of 100 slides)
09-02450	24 x 50	1000 pcs. (10 boxes of 100 slides)
09-02460	24 x 60	1000 pcs. (10 boxes of 100 slides)
09-05065	50 x 65	1000 pcs. (10 boxes of 100 slides)
09-030	Ø 30	1000 pcs. (10 boxes of 100 slides)

Distributor: Bio-Optica Milano S.p.A.



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## Functional features

Material:	hydrolytic glass class 1
Refraction index:	1.513 – 1.523 (measured between $\lambda = 546.07$ nm and $\lambda = 643.85$ nm)
Slide's thickness:	0.13 – 0.16 mm

The Cover Glasses Bio-Optica has a surface uniformly flat, without riflings, bubbles or scratches. Thanks to and automated production, the Cover Glasses are bare of dust or dirtiness, and allow a high optical quality, and a long and good maintenance in the time.

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## Storage and handling

- Keep dry.
- Avoid large variations in temperature during both storage and usage. Cooling of the product can cause condensation and lead to condensed water forming between the glasses.
- Please note: use older products in storage first.
- Protect the bottom of the carton from dampness.
- Slides shelf life: 12 month. See the expiry date on microscope slide packages.



Gerhard Menzel GmbH  
 Postfach 3157 · 38021 Braunschweig, Germany

## Declaration of conformity

We, Gerhard Menzel GmbH, Saarbrückener Str. 248, 38116 Braunschweig declare, that our

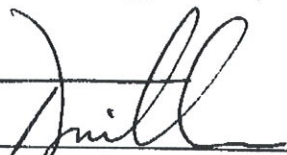
- Microscope slides and
- Cover glasses

fulfill the general requirements of the directive 98/79/EG on in-vitro-diagnostic medical devices from 27<sup>th</sup> October 1998, annex I and annex III.

Our microscope slides and cover glasses are manufactured underlying the following directives:

- ISO 8037-1: „Optic and optical instruments - Microscopes - Slides - Part 1: Dimensions, optical properties and marking“
- ISO 8255-1: „Optic and optical instruments - Microscopes – Cover glasses - Part 1: „Dimensional tolerances, thickness and optical properties“
- ISO 15223: „Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied“
- DIN EN 980: „Graphical symbols for use in the labelling of medical devices“
- BS 7011: „Consumable accessories for light microscopes“

Braunschweig, 22<sup>nd</sup> April 2010

  
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 Thomas Miller, General Manager



## Dichiarazione di conformità

Noi, Gerhard Menzel GmbH, Saarbruckener Str. 248, 38116 Braunschweig, dichiariamo che i nostri

- Vetrini portaoggetto per microscopia
- Vetrini coprioggetto

sono conformi ai requisiti generali richiesti dalla Direttiva 98/79/EC relativa ai Dispositivi medici Diagnostici in Vitro del 27 ottobre 1998, allegato I e allegato III.

I nostri vetrini portaoggetto e coprioggetto per microscopia sono prodotti in conformità alle seguenti direttive:

- ISO 8037-1: "Ottica e strumenti ottici - Microscopi - Vetrini - Parte 1: Dimensioni, proprietà ottiche e marcatura"
- ISO 8255-1: "Ottica e strumenti ottici - Microscopi - Vetrini coprioggetto - Parte 1: Tolleranza nelle dimensioni, spessore e proprietà ottiche"
- ISO 15223: "Dispositivi medici - Simboli da utilizzare per le etichette, le marcature e le informazioni da fornire relative ai dispositivi medici"
- DIN EN 980: "Simboli grafici utilizzati per l'etichettatura dei dispositivi medici"
- BS 7011: "Accessori consumabili per microscopi ottici"

Braunschweig, 22 Aprile 2010

Thomas Miller, Direttore Generale

