

SYNTESYS



SYNTESYS S.A.S. DI RINALDO R. & C.
VIA G. GALILEI, 10/3
35037 Z.I. SELVE DI TEOLO (PD)
TEL. +39 049 9903866 R.A. FAX +39 049 9903867

COD. FISCALE P.IVA N. REG. IMP. PADOVA 03573950288
E-MAIL INFO@SYNTESYS.IT - WEB WWW.SYNTESYS.IT

DICHIARAZIONE DI CONFORMITA'
Conformity declaration



Il sottoscritto, Rinaldo Ruggero legale rappresentante della ditta:
The undersigned, Rinaldo Ruggero legal representative of the company:

produttore/manufacturer

SYNTESYS S.a.s. di Rinaldo Ruggero & C.
indirizzo/address

Via G. Galilei, 10/3 35037 Zona Industriale SELVE DI TEOLO (PADOVA) ITALY

o rappresentante il mandatario autorizzato entro la Unione Europea or representing the
authorized mandatary within the European Community

Mandatario autorizzato/authorized mandatary

indirizzo/address

Dichiara sotto la propria responsabilità che il prodotto/declares under his own
responsability that the product:

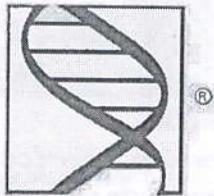
Denominazione degli
articoli
prodotti/Description of
Manufacturer

Contenitori per urina, contenitori per feci,
contenitori universali, Pipette Pasteur, Piastre di
Petri, Anse Sterili per batteriologia, Aste a "L",
Puntali Eppendorf gialli e blue, cuvette per
spettrofotometro, tazzine per campionamento siero,
bacchette per distacco ed estrazione del coagulo,
pinzette in polistirolo monouso, provette monouso in
plastica, tappi alettati per provette diam. 12 mm e
16mm, provette con granuli ed acceleratore, provette
sottovuoto per prelievo, Sistema SEDIPLAST,
Microprovette, Portavetrini, Vetrini precolorati,
Portaprovette, supporti per microprovette, bottiglie
per raccolta urine.

Urine container, faeces container, universal
container, Pasteur pipette, Petri dishes, Sterile
loops, Sterile loops open "L", Eppendorf tips yellow
and blue, cuvettes for spectrophotometer, samples
cups, Rod to detach clot, disposable forceps,
Disposable plastic tubes, winged stoppers for tubes
diam. 12mm & 16mm, Test tube with granules and clot
activator, vacuum test tube, SEDIPLAST system,
micro test tubes, Slides Mailer, "TESTSIMPLETS" slide,
rack for test tubes, rack for micro test tubes,
Bottles for urine collection.

PRODOTTI E STRUMENTAZIONE PER ANALISI DI LABORATORIO - DISPOSABLE LABWARE





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Materiale/Material

**Polipropilene, Polistirolo, Polietilene e
Polimetilmetacrilato**

***Polypropylene, Polystyrene, Polyethylene and
Polymethylmetacrylate***

È conforme alle disposizioni della direttiva 98/79/CE concernente i dispositivi medici diagnostici in vitro e recepita in Italia con D.L. del 08/09/2000 n° 332 allegato 1 (requisiti essenziali) ed è fabbricato in accordo ai requisiti di cui all'Allegato III della sopra citata direttiva / It meets the CE Directive 98/79 CE about in vitro diagnostic device specifications established by the Italian law n. 332, dated 8th September 2000. The device is made according to the specifications of the III attached of the above-mentioned directive.

Dichiara inoltre che la documentazione tecnica di supporto alla presente dichiarazione di conformità è conservata presso gli uffici dell'azienda e sarà posta alla disposizione di chi la richiede / declares that all technical documents attached to this conformity statement are filed in our company and can be consulted by any authorized body on demand.

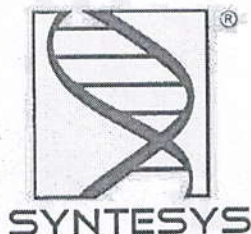
Data 07/01/2016

Issued on January 7th 2016

SYNTESYS S.a.s.
Il legale rappresentante
Rinaldo Ruggero



PRODOTTI E STRUMENTAZIONE PER ANALISI DI LABORATORIO - DISPOSABLE LABWARE



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or representing the authorized mandatary within the European Community

Mandatario autorizzato/authorized mandatary

indirizzo/address

Dichiara sotto la propria responsabilità che il prodotto/declares under his own
responsability that the product:

Denominazione/Description

Padella per ammalati, urinali uomo e donna, speculum vaginali,
tamponcini cotonati, tamponi sterili in provetta, tamponi sterili
con terreno Amies e Stuart in provetta/ Bed pan, Urinal's man and
woman, Vaginal speculum, Cotton swab, Sterile swab in test tube,
Sterile swab with medium Amies or Stuart in test tube

Materiale/Material

Polipropilene, Polietilene, Legno/ Polypropylene, Polyethylene,
Wood

È conforme alle disposizioni della direttiva 93/42/CE e s.m., concernente i dispositivi medici
ed al Decreto Legislativo di recepimento con D.lgs. del 24/02/1997 n° 46/97 e soddisfa a
tutti i requisiti specificati.

Il dispositivo è stato classificato appartenente alla classe I° secondo i criteri stabiliti
in base a quanto previsto dall'Art. 9 ed allegato IX della direttiva sopra citata /It meets
the EC Directive 93/42 about Medical Device, specifications established by the Italian law n
46/97, dated 24th February 1997. The device was classified as belonging to the 1st class,
according to the specifications of the established by the art.9, IX enclosure of the above
mentioned directive.

Dichiara inoltre che la documentazione tecnica di supporto alla presente dichiarazione di
conformità è conservata presso gli uffici dell'azienda e sarà posta alla disposizione di chi
la richiede/ declares that all technical documents attached to this conformity statement are
filed in our company and can be consulted by any authorized body on demand.

Data 07.01.2016
Issued on January 7th 2016

SYNTESYS S.A.S.
Il legale rappresentante
Rinaldo Ruggero



PRODOTTI E STRUMENTAZIONE PER ANALISI DI LABORATORIO - DISPOSABLE LABWARE



THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

CISQ/ICIM SPA has issued an IQNet recognized certificate that the organization:

SYNTESYS S.a.s.
di Rinaldo Ruggero e C.

Via G. Galilei, 10/3 - Zona Industriale - I-35037 Selve di Teolo (PD)

has implemented and maintains a
Quality Management System

for the following scope:

Trading of products for laboratory analysis.
Manufacturing of products for laboratory analysis and sanitary products.

which fulfils the requirements of the following standard:

ISO 9001:2015

Issued on: **2019-06-05**
First issued on: **2013-06-05**
Expires on: **2022-06-04**

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-83562



Alex Stoichitoiu
President of IQNET



Ing. Claudio Provetti
President of CISQ

IQNet Partners*:

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 FGA Brazil
FONDONORMA Venezuela ICONTEC Colombia Inspecta Sertifointi Oy Finland INTECO Costa Rica
IRAM Argentina IQA Japan KFQ Korea MIRTEC Greece MSZT Hungary Nemko AS Norway NSAI Ireland
NYCE-SIGE Mexico 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 UIC Serbia
IQNet is represented in the USA by: AFNOR Certification, CISQ, DQS Holding GmbH and NSF Inc.





THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

CISQ/ICIM SPA has issued an IQNet recognized certificate that the organization:

SYNTESYS S.a.s.
di Rinaldo Ruggero e C.

Via G. Galilei, 10/3 - Zona Industriale - I-35037 Selve di Teolo (PD)

has implemented and maintains a
Quality Management System

for the following scope:

Trading of products for laboratory analysis.
Manufacturing of products for laboratory analysis and sanitary products.

which fulfils the requirements of the following standard:

ISO 13485:2016

Issued on: **2019-06-05**
First issued on: **2014-06-21**
Expires on: **2022-06-04**

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-93779



Alex Stoichitoiu
President of IQNET



Ing. Claudio Provetti
President of CISQ

IQNet Partners*:

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 ICAY Brazil
FONDONORMA Venezuela ICONTEC Colombia Inspecta Sertifiointi Oy Finland INTECO Costa Rica
IRAM Argentina IQA Japan KFQ Korea MIRTEC Greece MSZT Hungary Nemko AS Norway NSAI Ireland
NYCE-SIGE Mexico 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 TUCS Serbia
IQNet is represented in the USA by: AFNOR Certification, CISQ, DQS Holding GmbH and NSAI Inc.



« CE » CERTIFICATE OF COMPLIANCE

We, interscience, guarantee that the following products:

MiniMix® 100 VP
MiniMix® 100 VW
MiniMix® 100 CC
CoolMix® 100 VP

JumboMix® 3500 VP
JumboMix® 3500 VW
JumboMix® 3500 VW
WarmMix

easySpiral®
easySpiral Pro®
easySpiral Pro Milk®
easySpiral Dilute®

BagMixer® 400 P
BagMixer® 400 W
BagMixer® 400 CC
BagMixer® S
BagMixer® SW
iMix®

DiluFlow®
DiluFlow® Pro
DiluFlow® Elite

FlexiPump®
FlexiPump® Pro

Scan® 100
Scan® 300
Scan® 500
Scan® 1200
Scan® 4000

ScanStation® 100
ScanStation® 200
ScanStation® 300

are in compliance with the following directives:

- European Directive 2006/42/EC relating to machines.
- European Directive 2014/30/UE about electromagnetic compatibility.
- European Directive 2014/35/UE relating to low voltage electrical goods

St Nom-la-Bretèche,
January 15th, 2020



Emmanuel JALENQUES
Co-CEO



Certificate of Approval

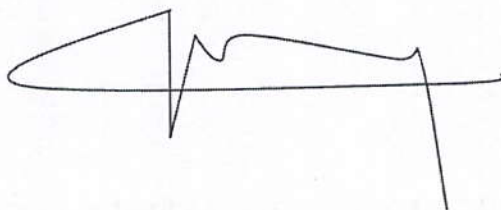
This is to certify that the Management System of:

INTERLAB

Route de Jalenques, 15340 MOURJOU, France

has been approved by LRQA to the following standards:

ISO 9001:2015



Gilles Bessiere - Area Technical Manager

Issued By: LRQA France SAS

for and on behalf of: Lloyd's Register Quality Assurance Limited

Current Issue Date: 1 July 2018
Expiry Date: 29 June 2021
Certificate Identity Number: 10089334

Original Approvals:
ISO 9001 – 6 June 1997

Approval Number(s): ISO 9001 – 0031503

The scope of this approval is applicable to:
Design and manufacturing of equipment, bags and filter bags for laboratories. Packaging of products and laboratory equipment on behalf of INTERSCIENCE.



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