



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

0 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 responsibility 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, Portavatrini, 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 recepito 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



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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

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CQC China CQM China CQS Czech Republic Cro Cert Croatia DQS Holding GmbH Germany FCAV Brazil
FONDONORMA Venezuela ICONTEC Colombia Inspecta Sertifiointi Oy Finland INTECO Costa Rica
IRAM Argentina JQA 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 YUQS Serbia
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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

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SIRIM QAS International Malaysia SQS Switzerland SRAC Romania TEST St Petersburg Russia TSE Turkey YUQS Serbia
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