

SYNTESSYS 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@SYNTESSYS.IT - WEB WWW.SYNTESSYS.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

SYNTESSYS S.a.s. di Rinaldo R. & 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/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 smi, 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.

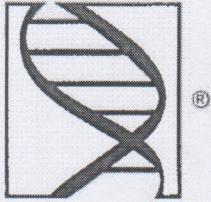
Il dispositivo è stato classificato appartenente alla classe I° secondo i criteri stabiliti in base a quanto previsto dall'Art. 9 ed allegato IX della direttiva sopra citata /It meets the EC Directive 93/42 about Medical Device, specifications established by the Italian law n 46/97, dated 24th February 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 statment are filed in our company and can be consulted by any authorized body on demand.

Data 07.01.2016
Issued on January 7th 2016



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



SYNTESYS



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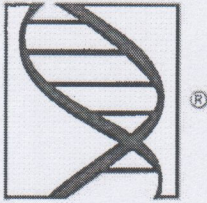
Dichiara sotto la propria responsabilità che il prodotto/*declares under his own responsibility that the product:*

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, 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.





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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 I (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.*

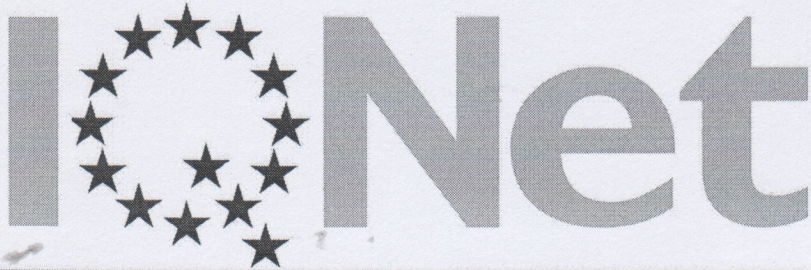
Dichiara inoltre che la documentazione tecnica di supporto alla presente dichiarazione di conformità è conservata presso gli uffici dell'azienda e sarà posta alla disposizione di chi la richiede / *declares that all technical documents attached to this conformity statement are filed in our company and 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



®



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
Alex Stoichitoiu
President of IQNET



Ing. Claudio Provetti
Ing. Claudio Provetti
President of CISQ

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



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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
Alex Stoichitoiu
President of IQNET



Ing. Claudio Provetti
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 Sertifointi 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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