



DICHIARAZIONE DI CONFORMITA' UE EU DECLARATION OF CONFORMITY

conforme all'Allegato IV del Regolamento (UE) 2017/746 "Dispositivi medico-diagnostici in vitro"
according to Annex IV of the Regulation (EU) 2017/746 "In vitro diagnostic medical devices"

fabbricante **ROLL S.R.L.**
manufacturer **articoli per laboratori analisi - disposable labware**
N° registrazione unico **IT-MF-000021270**
SRN
indirizzo **Via Leonardo da Vinci, 24/A,**
address **35028 PIOVE DI SACCO (PD) - ITALIA**
telefono **+39-0499719511** fax **+39-0499719543** posta elettronica **roll@tecnomeus.it**
phone fax e-mail

Identificazione dei prodotti **PROVETTE PST 16X100 MM 10 ML CONICHE CON BORDO**

Product identification **PS CONICAL TEST TUBES 16X100 MM 10 ML WITH RIM**

Destinazione d'uso **CAMPIONAMENTO DI LIQUIDI BIOLOGICI**
Intended use **SAMPLING OF BIOLOGIC LIQUIDS**

BASIC UDI-DI **805938689TTUBEVZ**

CND **W050301020102**

numero di catalogo **18304** numero di lotto **23046** scadenza **30/06/2027**
part number batch number expiry date

classificazione dei prodotti **dispositivi non sterili rientranti nella classe A del regolamento 2017/746, conforme alla regola 5**
product identification **non sterile devices included in the class A regulation (EU) 2017/746, according to rule 5**

Si dichiara

sotto la propria esclusiva responsabilità che tutti i dispositivi sopraelencati rispettano le disposizioni applicabili dal regolamento 2017/746 Dispositivi Medico-Diagnostici In Vitro.

La documentazione tecnica richiesta dal suddetto regolamento e quella comprovante il rispetto dei Requisiti generali di sicurezza e prestazione di cui all'Allegato I del Regolamento, sono conservati a cura del Fabbricante

Hereby we declare

Under our sole responsibility that the above mentioned devices meet the applicable provisions of the Regulation (EU) 2017/746 on "In vitro diagnostic medical devices"

The technical documentation, as required by Regulation (EU) 2017/746 and documents in order to prove conformity to general safety and performance requirements as listed in Annex I, are retained under the premises of the Manufacturer

luogo e data **PIOVE DI SACCO, 30/07/2022**
place and date

firma **ROLL S.R.L.**
signature **Quality Assurance**
Giovanni Chiarin

Giovanni Chiarin

Certificate

CISQ/ICIM S.P.A. has issued an IQNet recognized certificate that the organization:

SYNTESYS S.R.L.

Head Office and Operative Unit

Via G. Galilei, 10/1-2-3 - Zona Industriale - I-35037 Selve di Teolo (PD)

Operative Units

Via G. Galilei, 16/1 - Zona Industriale - I-35037 Selve di Teolo (PD)

Via San Benedetto, 48/A - Zona Industriale - I-35037 Selve di Teolo (PD)

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

has implemented and maintains a/an

Quality Management System

for the following scope:

Trading of products for laboratory analysis. Manufacturing of products for laboratory analysis and sanitary products. Design and production management of sterile swabs for the collection and the preservation of biological samples, also for surgical application, with or without transport medium.

which fulfils the requirements of the following standard:

ISO 9001:2015

Issued on: **2022-06-05**

First issued on: **2013-06-05**

Expires on: **2025-06-04**

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


Mario Romersi
President of CISQ



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LSQA Uruguay **MIRTEC** Greece **MSZT** Hungary **Nemko AS** Norway **NSAI** Ireland **NYCE-SIGE** México **PCBC** Poland **Quality Austria**
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Trading of products for laboratory analysis. Manufacturing of products for laboratory analysis and sanitary products. Design and production management of sterile swabs for the collection and the preservation of biological samples, also for surgical application, with or without transport medium.

which fulfils the requirements of the following standard:

ISO 13485:2016

Issued on: **2022-06-05**

First issued on: **2014-06-21**

Expires on: **2025-06-04**

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



Mario Romersi
President of CISQ



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SYNTESYS S.R.L. UNIPERSONALE

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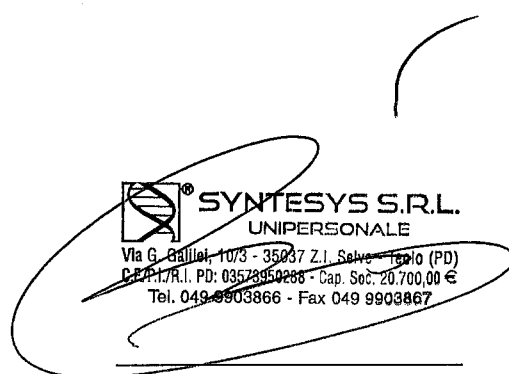
AUTHORIZATION LETTER

We, **Syntesys S.R.L.** having a registered office at Via G. Galilei 10/3, 35037 Selve di Teolo - PD - Italy, assign **Sanmedico SRL** having a registered office at A.Corobceanu str., apt. 9, Chişinău MD-2012, Moldova, as authorized representative.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

This letter is valid till 31.12.2021

Teolo, 05.01.2021



 **SYNTESYS S.R.L.**
UNIPERSONALE
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C.F./P.I./R.I. PD: 03573950288 - Cap. Soc. 20.700,00 €
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Rinaldo Ruggero
CEO and Legal Representative
SYNTESYS S.R.L.