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CERTIFICAT Nr. DM/24/277/S

CERTIFICATE No.

SE CERTIFICĂ SISTEMUL DE MANAGEMENT AL CALITĂŢII AL

IT IS HEREBY CERTIFIED THAT THE QUALITY MANAGEMENT SYSTEM OF

TODY LABORATORIES MED S.R.L.

STR. VADUL MOLDOVEI NR. 22, SECTOR 1, CAM. 3, ET. 2, AP. 3, 014033, BUCURESTI, ROMANIA

Pentru informaţii privind valabilitatea certificatului, vizitaţi site-ul www.rina.org

For information concerning validity of the certificate, you can visit the site www.rina.org

ÎN URMĂTOARELE UNITĂŢI OPERAŢIONALE / *IN THE FOLLOWING OPERATIONAL UNITS*

STR. VADUL MOLDOVEI NR. 22, SECTOR 1, CAM. 3, ET. 2, AP. 3, 014033, BUCURESTI, ROMANIA

CARE ESTE CONFORM CU STANDARDUL / *IS IN COMPLIANCE WITH THE STANDARD*

ISO 13485:2016

Certificatul transpune actualizarea reglementarii referitoare la standardul EN ISO 13485:2021 aplicabil în Spațiul Economic European

The certificate transposes the regulatory update relating to the EN ISO 13485:2021 standard applicable in the European Economic Area

PENTRU URMĂTOARELE DOMENII DE ACTIVITATE / *FOR THE FOLLOWING FIELD(S) OF ACTIVITIES*

IMPORT SI DISTRIBUTIE DISPOZITIVE MEDICALE GENERALE INACTIVE, NEIMPLANTABILE SI DISPOZITIVE MEDICALE DE DIAGNOSTIC IN VITRO (REACTIVI, CONSUMABILE SI APARATE)

IMPORT AND DISTRIBUTION OF NON-ACTIVE, NON-IMPLANTABLE GENERAL MEDICAL DEVICES AND IN VITRO DIAGNOSTIC MEDICAL DEVICES (REAGENTS, CONSUMABLE AND DEVICES)

Validitatea prezentului certificat depinde de auditurile de supraveghere periodice anuale / semestriale şi de reexaminarea completă a sistemului de management la trei ani

The validity of this certificate is dependent on an annual / six monthly audit and on a complete review, every three years, of the management system

Făcând referire la Manualul Calităţii privind excluderile din cerintele standardului

Reference is to be made to the Quality Manual for details regarding the exemptions from the requirements of the standard

Utilizarea şi validitatea prezentului certificat sunt supuse respectarii documentului RINA: Regulament privind Certificarea Sistemelor de Management al Calităţii in sectorul Dispozitivelor Medicale

The use and validity of this certificate are subject to compliance with the RINA document: Rules for the certification of Quality Management Systems in the Medical Devices sector

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ACCREDIA
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CISQ is the Italian Federation of management system Certification Bodies

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IQNET

Building trust together.

Certificate

CISQ / RINA has issued an IQNET recognized certificate that the organization:

TODY LABORATORIES MED S.R.L.

STR. VADUL MOLDOVEI NR. 22, SECTOR 1, CAM. 3, ET. 2, AP. 3, 014033, BUCURESTI, ROMANIA

has implemented and maintains a/an

Medical Devices - Quality Management System

for the following scope:

IMPORT AND DISTRIBUTION OF NON-ACTIVE, NON-IMPLANTABLE GENERAL MEDICAL DEVICES AND IN VITRO DIAGNOSTIC MEDICAL DEVICES (REAGENTS, CONSUMABLE AND DEVICES)

which fulfills the requirements of the following standard:

ISO 13485:2016

Issued on: **2024-01-10**

First Issued on: **2024-01-10**

Expires on: **2027-01-09**

All details about any legal entities, operative units and related activities included in this certificate are contained in CISQ/RINA original certificate no.: **DM/24/277/S**

Registration Number: **IT-148346**

Alex Stoichitoiu
President of IQNET

Mario Romersi
President of CISQ

CISQ

This attestation is directly linked to the IQNET Member's original certificate and shall not be used as a stand-alone document.

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