



March 18th, 2025

Declaration Letter

To Whom It May Concern:

We, ACON Laboratories, Inc., with a registered office at 5850 Oberlin Drive #340, San Diego, CA 92121, authorize SRL Sanmedico, with a registered office at A. Corobceanu Street 7A, Apt. 9, Chişinău, MD-2012, Moldova, to register, notify, renew, or modify the registration of medical devices in the territory of the Republic of Moldova.

Sincerely,

A handwritten signature in black ink, appearing to read "Qiyi Xie", is written over a horizontal line.

Qiyi Xie
V.P. of Regulatory Affairs & Clinical Affairs
ACON Laboratories, Inc.





Certificate

No. Q5 104507 0001 Rev. 03

Holder of Certificate: **ACON Laboratories, Inc.**
5850 Oberlin Drive, #340
San Diego CA 92121
USA

Certification Mark:



Scope of Certificate: **Design and Development, Manufacture and distribution of In Vitro Diagnostic Test Kits and Reagents for the Determination of Infectious Diseases, Clinical Chemistry, Drugs of Abuse, Tumor/Cardiac Marker, Fertility/Pregnancy and Blood Glucose Monitoring System, Lancing Devices and Lancets**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 104507 0001 Rev. 03

Report No.: SH22743A01

Valid from: 2022-09-15
Valid until: 2025-09-06

Date, 2022-09-15

Christoph Dicks
Head of Certification/Notified Body

Certificate

No. Q5 104507 0001 Rev. 03

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

ACON Laboratories, Inc.
5850 Oberlin Drive, #340, San Diego CA 92121, USA

Address holder for registration only

ACON Laboratories, Inc.
10125 Mesa Rim Road, San Diego CA 92121, USA

Manufacture and distribution of
In Vitro Diagnostic Test Kits and Reagents for the Determination of
Infectious Diseases, Clinical Chemistry, Drugs of Abuse,
Tumor/Cardiac Marker, Fertility/Pregnancy and Blood Glucose
Monitoring System, Lancing Devices and Lancets

ACON Laboratories, Inc.
6865 Flanders Dr., Suite B, San Diego CA 92121, USA

Storage of
In Vitro Diagnostic Test Kits and Reagents for the Determination of
Infectious Diseases, Clinical Chemistry, Drugs of Abuse,
Tumor/Cardiac Marker, Fertility/Pregnancy and Blood Glucose
Monitoring System, Lancing Devices and Lancets

AZURE Institute, Inc.
10125 Mesa Rim Road, San Diego CA 92121, USA

Design and Development of
In Vitro Diagnostic Test Kits and Reagents for the Determination of
Infectious Diseases, Clinical Chemistry, Drugs of Abuse,
Tumor/Cardiac Marker, Fertility/Pregnancy and Blood Glucose
Monitoring System, Lancing Devices and Lancets

Acon Laboratories Inc.
Guerrero Negro 9942 Parque Industrial Pacifico IV, 22644
Tijuana B.C. CP, MEXICO

Manufacture of
blood glucose test strips, antigen rapid test and IgG/IgM antibody
rapid test for infectious disease.



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-245.10.07



Product Service

EC Certificate

Full Quality Assurance System

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 104507 0003 Rev. 06

Manufacturer:

ACON Laboratories, Inc.

5850 Oberlin Drive, #340
San Diego CA 92121
USA

**Product Category(ies): Blood glucose measuring systems for self testing
and self-testing devices for clinical chemistry,
hematology and pregnancy and ovulation**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device families in accordance with IVDD Annex IV. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of List A devices an additional Annex IV (4) certificate is mandatory. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:V1 104507 0003 Rev. 06](http://www.tuvsud.com/ps-cert?q=cert:V1_104507_0003_Rev.06)

Report no.:

SH22743EXT01

Valid from:

2022-05-04

Valid until:

2025-05-26

Date,

2022-05-04

Christoph Dicks
Head of Certification/Notified Body



EC Certificate

Full Quality Assurance System

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 104507 0003 Rev. 06

Model(s):

On Call Plus Blood Glucose Monitoring System,
On Call Plus Blood Glucose Test Strips,
On Call EZ II Blood Glucose Monitoring System,
On Call Advanced Blood Glucose Monitoring System,
On Call Advanced Blood Glucose Test Strips,
On Call Chosen Blood Glucose Test Strips,
On Call Vivid Blood Glucose Monitoring System (OGM-101),
On Call Vivid Blood Glucose Test Strips (OGS-101),
On Call Sharp Blood Glucose Monitoring System (OGM-121),
On Call Sharp Blood Glucose Test Strips (OGS-121)
On Call Plus II Blood Glucose Monitoring System (OGM-171),
On Call Plus II Blood Glucose Test Strips (OGS-171),
On Call Extra Blood Glucose Monitoring System (OGM-191),
On Call Extra Blood Glucose Test Strips (OGS-191),
On Call GK Dual Blood Glucose & Ketone Monitoring System (OGM-161),
On Call Blood Ketone Test Strips (OGS-161),
Urinalysis Reagent Strips (Urine),
UTI Urinary Tract Infection Test Strips,
Cholesterol Monitoring System (CCM-111),
CHOL Total Cholesterol Test Devices (CCS-111),
TRIG Triglycerides Test Devices (CCS-112),
HDL High Density Lipoprotein Test Devices (CCS-113),
3-1 Lipid Panel Test Devices (CCS-114),
Cholesterol CTRL Control Devices,
Cholesterol Monitoring System (CCM-101),
CHOL Total Cholesterol Test Strips (CCS-101),
PT/INR Monitoring System (CCM-151),
PT/INR Test Strips (CCS-151),
Hemoglobin Testing System (CCM-141),
Hemoglobin Test Strips (CCS-141),
hCG Pregnancy Rapid Test Cassette (Urine),
Pregnancy Rapid Test Midstream,
On Call Extra Mobile Blood Glucose Monitoring System (OGM-281),
On Call Sure Blood Glucose Monitoring System (OGM-211),
On Call Sure Sync Blood Glucose Monitoring System (OGM-212),
On Call Sure Blood Glucose Test Strips (OGS-211),
GIMA Blood Glucose Monitoring System,
GIMA Bluetooth Blood Glucose Monitoring System,
GIMA Blood Glucose Test Strips,
On Call GU Dual Blood Glucose & Uric Acid Monitoring



EC Certificate

Full Quality Assurance System

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 104507 0003 Rev. 06

System (OGM-201),
On Call Blood Uric Acid Test Strips (OGS-201),
LH Ovulation Rapid Test Cassette (Urine),
Ovulation Rapid Test Midstream,
Ovulation & Pregnancy Test Combo Pack,
On Call Extra Voice Blood Glucose Monitoring System
(OGM-291),
Early Detection Pregnancy Test,
Digital Pregnancy Test,
Go-Keto Blood Glucose & Ketone Monitoring System (OGM-
161),
Go-Keto Blood Ketone Test Strips (OGS-161),
Go-Keto Blood Glucose Test Strips,
On Call Extra GM Blood Glucose Monitoring System(OGM-
191),
On Call Extra GM Blood Glucose Test Strips (OGS-191),
On Call Plus GM Blood Glucose Monitoring System,
On Call Plus GM Blood Glucose Test Strips,
Go-Keto Urinalysis Reagent Strips

Facility(ies):

ACON Laboratories, Inc.
5850 Oberlin Drive, #340, San Diego CA 92121, USA

ACON Laboratories, Inc.
10125 Mesa Rim Road, San Diego CA 92121, USA

AZURE Institute, Inc.
10125 Mesa Rim Road, San Diego CA 92121, USA

Acon Laboratories Inc.
Guerrero Negro 9942 Parque Industrial Pacifico IV, 22644 Tijuana
B.C. CP, MEXICO

Declaration of Conformity

We, the manufacturer, under compliance to Article 17 of regulation (EU) 2017/746, declare under our sole responsibility that the medical device:

Device Name	REF Number
Mission® U500 Urine Analyzer	U211-101, U211-111
Mission® U500 Data Transfer Kit	U221-131
Mission® Urine Analyzer Barcode Reader	U221-111
Mission® Printer Paper Rolls	U121-101

of class A according to Rule 5(b) of Annex VIII of regulation (EU) 2017/746, is in conformity with

Regulation (EU) IVDR 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU

and

Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, and further amendments to the directive issued and in force at the date of this declaration.*

It has been demonstrated that the requirements specified in Article 4 have been met.

The materials in ACON's products are assessed in accordance with ACON's procedure for approval which uses documents and contractual agreements to evaluate compliance and approve new materials and components.*

This declaration is based on:

Manufacturer's Name: ACON Laboratories, Inc.

Manufacturer's Address: 5850 Oberlin Drive, #340 San Diego, CA 92121

Manufacturer's SRN: US-MF-000023913

Authorized Representative Name: Medical Device Safety Service GmbH

Authorized Representative Address: Schiffgraben 41, 30175 Hannover, Germany

Basic UDI-DI: 68260799999900424B

Intended Purpose of device: The U500 Urine Analyzer is intended for use in conjunction with the Urinalysis Reagent Strips for the semi-quantitative detection of the following analytes in human urine: Glucose, Bilirubin, Ketone (Acetoacetic acid), Specific Gravity, Blood, pH, Protein, Urobilinogen, Leukocytes, Ascorbic Acid, Albumin, Creatinine, and Calcium, as well as the qualitative detection of Nitrite. The instrument is intended for professional, in vitro diagnostic use only.

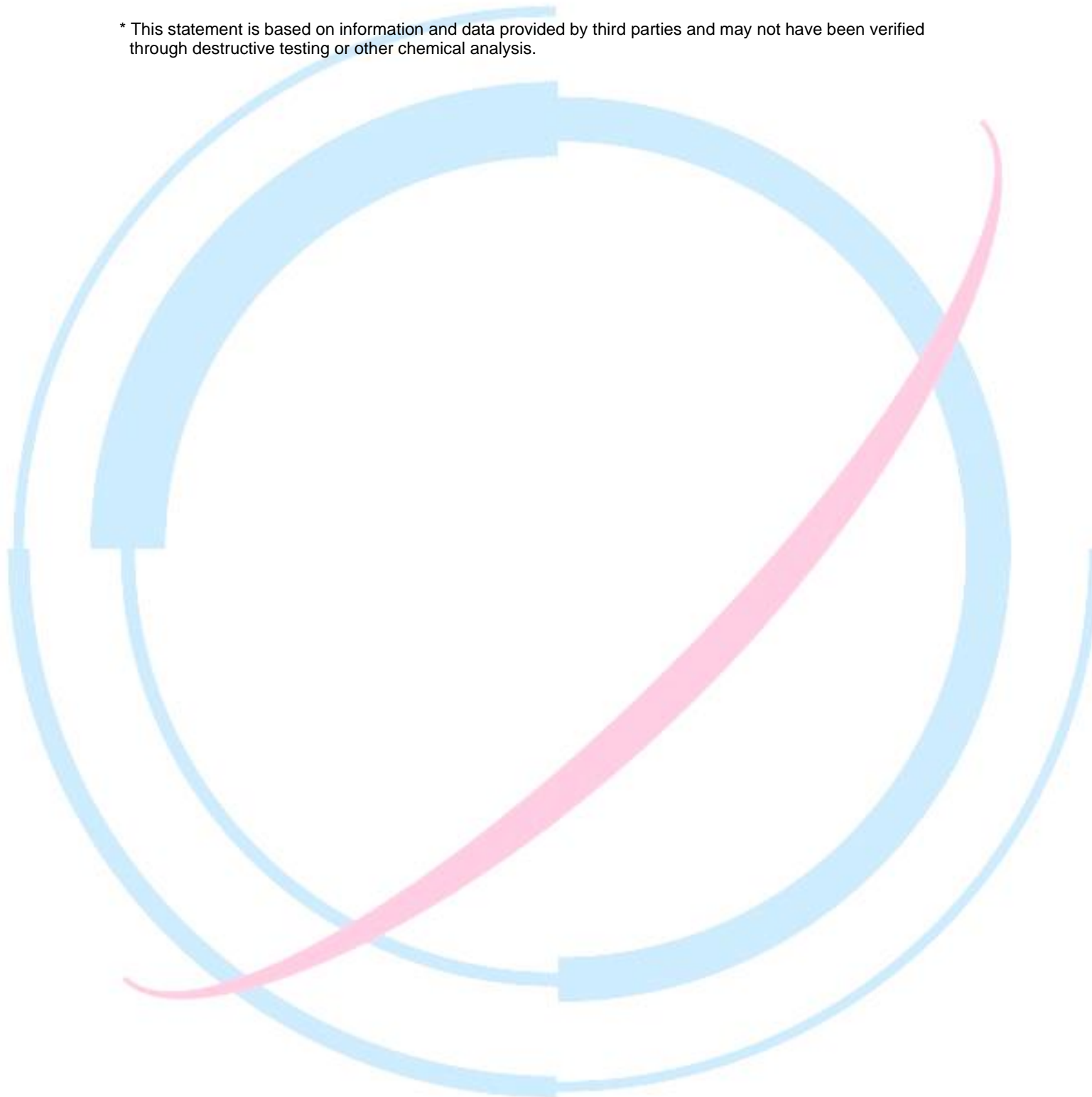
Signed this 20 day of May, 2022
in San Diego, CA USA





Qiyi Xie, MD, MPH
Senior Staff, Regulatory Affairs & Clinical Affairs
ACON Laboratories, Inc.

* This statement is based on information and data provided by third parties and may not have been verified through destructive testing or other chemical analysis.



5850 Oberlin Drive #340-San Diego, CA 92121, USA • Tel: (858) 875-8000 • Fax: (858) 875-8099
E-mail: info@aconlabs.com



ACON Laboratories, Inc.

10125 Mesa Rim Road. • San Diego, CA 92121 • USA
Tel: (858) 875-8000 • Fax: (858) 875-8099 • E-mail: info@aconlabs.com

November 11th 2016

CERTIFICATION LETTER

This letter is to certify that, Vitalie Goreacii, employed by Sanmedico SRL located at: Republic of Moldova, city Chisinau, str. Petricani 88/1 of. 10, MD-2059, have received all required training and is enabled and authorized to provide services with installation, commissioning, and maintenance to the products listed below:

Mission® U120 Urine Analyzer
Mission® U120 Ultra Urine Analyzer
Mission® U500 Urine Analyzer
Mission® PT/INR Coagulation Monitoring System
Mission® Cholesterol Monitoring System
Mission® Ultra Cholesterol Monitoring System
Mission® HB Hemoglobin Testing System
Mission® Plus HB Hemoglobin Testing System
OnCall® Glucose Meter

For further questions or inquiries regarding this matter, please refer to the contact information below.

Sincerely

A handwritten signature in black ink, appearing to read "Jassy Alvarenga", is written over a red circular stamp.

Jassy Alvarenga
International Account Manager
ACON Laboratories, Inc. S.A.

jalvarenga@aconlabs.com

+1 858 875 8085



Certificate of Completion

Presented to

Ms. POHILCO Irina

for successfully completing the training
course on operating and setting up the
Mission U500 and Mission U500 Expert
Urine Analyzers

Certified Trainer: **Catherine Lemercier** *Catherine Lemercier*

Dated: **March 14, 2024** 03/14/2024



aconlabs.com

ACON Laboratories, Inc.
10125 Mesa Rim Road, San Diego, CA 92121, U.S.A.
Tel: 1.858.875.8000
Fax: 1.858.200.0729
Email: info@aconlabs.com

Document History

SignNow E-Signature Audit Log

All dates expressed in MM/DD/YYYY (US)

Document name: POHILCO Irina U500 certificate
Document created: 03/14/2024 15:29:35
Document pages: 1
Document ID: 65857ac4c62e4fc69e3a296db92f74953df6f03e
Document Sent: 03/14/2024 15:33:16 UTC
Document Status: Signed
03/14/2024 15:33:36UTC

Sender: clemercier@aconlabs.com
Signers: clemercier@aconlabs.com
CC: pcavaliere@aconlabs.com

Client	Event	By	Server Time	Client Time	IP Address
SignNow Web Application	Uploaded the Document	clemercier@aconlabs.com	03/14/2024 15:29:35 pm UTC	03/14/2024 15:29:30 pm UTC	172.10.130.177
SignNow Web Application	Viewed the Document	clemercier@aconlabs.com	03/14/2024 15:32:28 pm UTC	03/14/2024 15:32:27 pm UTC	172.10.130.177
SignNow Web Application	Viewed the Document	clemercier@aconlabs.com	03/14/2024 15:32:36 pm UTC	03/14/2024 15:32:36 pm UTC	172.10.130.177
SignNow Web Application	Document Saved	clemercier@aconlabs.com	03/14/2024 15:32:57 pm UTC	03/14/2024 15:32:57 pm UTC	172.10.130.177
SignNow Web Application	Invite Sent to: clemercier@aconlabs.com	clemercier@aconlabs.com	03/14/2024 15:33:16 pm UTC	03/14/2024 15:33:16 pm UTC	172.10.130.177
SignNow Web Application	User logged in	clemercier@aconlabs.com	03/14/2024 15:33:19 pm UTC	03/14/2024 15:33:18 pm UTC	172.10.130.177
SignNow Web Application	Viewed the Document	clemercier@aconlabs.com	03/14/2024 15:33:19 pm UTC	03/14/2024 15:33:18 pm UTC	172.10.130.177
SignNow Web Application	Signer Authenticated Using Password	clemercier@aconlabs.com	03/14/2024 15:33:24 pm UTC	03/14/2024 15:33:24 pm UTC	172.10.130.177
SignNow Web Application	Added a Text	clemercier@aconlabs.com	03/14/2024 15:33:36 pm UTC	03/14/2024 15:33:36 pm UTC	172.10.130.177
SignNow Web Application	Document Saved	clemercier@aconlabs.com	03/14/2024 15:33:36 pm UTC	03/14/2024 15:33:36 pm UTC	172.10.130.177
SignNow Web Application	Signed the Document	clemercier@aconlabs.com	03/14/2024 15:33:36 pm UTC	03/14/2024 15:33:36 pm UTC	172.10.130.177

TO WHOM IT MAY CONCERN

To any governmental departments,
registration and/or trade offices in MOLDOVA

Distribution Authorisation Letter

This letter confirms that

Sanmedico
Mun. Chisinau
Str. Petricani 88/1 of. 10
Republica MOLDOVA

is the **legal, exclusive and sole** representative of **TECO Medical Instruments Production + Trading GmbH, Dieselstr. 1, 84088 Neufahrn NB, Germany**, for the territory of **MOLDOVA** only for all TECO products listed below. **Sanmedico** may participate in public and private tenders, providing sales to all TECO customers in the territory. We as manufacturer certify that our warranty is duly passed to the purchaser through **Sanmedico** for the price, delivery schedules and the specifications of the published literature, catalogues and fully covering the commodities offered.

Sanmedico will provide the following information to TECO GmbH when so required in relation to its market surveillance activities:

Reporting of incidents to TECO must take place within 3 working days

Serial number of the device, exact location of the device and the user.

Validity: January 1st, 2025 to December 31st, 2026

Termination: Confirmation ends automatically on Dec. 31st of 2026
and must be then renewed.

Products:

- | | |
|--|---|
| • Coatron M1 | Semi-automated 1-channel Coagulometer (out of production) |
| • Coatron M2 | Semi-automated 2-channel Coagulometer (out of production) |
| • Coatron X Eco | Semi-automated 1-channel Coagulometer |
| • Coatron X Pro | Semi-automated 2-channel Coagulometer |
| • Coatron X Top | Semi-automated 4-channel Coagulometer |
| • Coatron A4 | Fully automated Coagulometer, 4 optic channels |
| • Coatron A6 | Fully automated Coagulometer, 6 optic channels |
| • Coatron A6 plus | Fully automated Coagulometer, 6 optic channels |
| all instruments with complete accessory, consumables and spare parts | |
| • Hemostasis Reagents | Complete product line |

This document is signed in Neufahrn, Germany, on December 3th, 2024

TECO Medical Instruments Production+Trading GmbH


Christian Hoetzl
General Management



Certificate of Approval

This is to certify that the Management System of:

TECO Medical Instruments, Production + Trading GmbH

Dieselstr. 1, 84088 Neufahrn, Germany

has been approved by LRQA to the following standards:

ISO 13485:2016

Approval number(s): ISO 13485 – 00038268

The scope of this approval is applicable to:

Design, development, manufacturing, storage and sales of coagulation instruments and in-vitro-diagnostic reagents used in the hemostaseology and coagulation.



Paul Graaf

Area Operations Manager, Europe

Issued by: LRQA Limited



0001

LRQA Group Limited, its affiliates and subsidiaries and their respective officers, employees or agents are, individually and collectively, referred to in this clause as 'LRQA'. LRQA assumes no responsibility and shall not be liable to any person for any loss, damage or expense caused by reliance on the information or advice in this document or howsoever provided, unless that person has signed a contract with the relevant LRQA entity for the provision of this information or advice and in that case any responsibility or liability is exclusively on the terms and conditions set out in that contract.

Issued by: LRQA Limited, 1 Trinity Park, Bickenhill Lane, Birmingham B37 7ES, United Kingdom



KONFORMITÄTSERKLÄRUNG DECLARATION OF CONFORMITY

Doc#001-01/06-2022

Hersteller / Manufacturer:

**TECO Medical Instruments
Production and Trading GmbH**

Adresse / Address:

Dieselstrasse 1, 84088 Neufahrn, Germany

Marktakteur / Actor ID SRN:

DE-MF-000022642 <https://ec.europa.eu>

Die hier benannten Produkte der generischen Produktgruppe erfüllen die Anforderungen der aufgeführten Verordnungen, Richtlinien und Normen. Im Falle eigenmächtiger Veränderungen am Produkt oder der nicht bestimmungsgemäßen Verwendung verliert diese Erklärung ihre Gültigkeit.

Diese Konformitätserklärung wird unter der alleinigen Verantwortung des Herstellers ausgestellt.

BASIS UDI-DI 426018278CMX81152

IVD - halb-automatische Blutgerinnungsmessgeräte - Handelsbezeichnung, Typ, Kat.-Nr.

IVD - semi-automated Coagulation Systems - trade name, type, model, Cat.-No.

Coatron X Eco / Coatron X Pro / Coatron X Top

81 101 10

81 101 20

81 101 40

The products of the generic product group named here fulfil the requirements of listed regulations, directives and standards. In the case of unauthorised modifications to the product or use not in accordance with the intended purpose, this declaration becomes invalid.

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Verordnung (EU) 2017/746

für in-vitro Diagnostika-IVDR

und dem harmonisierten Standard am 2022-05-12:

Risikoklassifizierung gemäß Artikel 47-Anhang VIII

Regel 5 b – „Klasse A“

Konformitätsbewertungsverfahren gemäß:

(EU) 2017/746 Artikel 17 (Anhang II+III)

Angewandte Normen zur Sicherstellung der grundlegenden Anforderungen an Leistung und Sicherheit:

EN ISO 18113-3:2011

DIN EN 62304:2018

DIN EN 62366-1

DIN EN 62366-1:2017

DIN EN 61326-1:2013

DIN EN 55011:2009 + A1:2010

IEC 61010-1:2010, AMD1:2016

IEC 61010-2-101:2015

IEC 61010-1:2010

Richtlinie 2011/65/EU RoHS III

(incl. (EU) 2015/863) - DIN EN IEC 63000

QM-System gemäß (EU) 2017/746 Art.10(8)

angewandter Standard: EN ISO 13485:2021

Regulation (EU) 2017/746

for In-vitro diagnostic medical devices

and it's harmonized standard at 2022-05-12:

Risk classified according to article 47 annex VIII

Rule 5 b – "Class A"

Conformity assessment procedure in accordance with:

(EU) 2017/746 Article 17 (annex II+III)

Standards applied to ensure the essential requirements for performance and safety:

EN ISO 18113-3:2011

DIN EN 62304:2018

DIN EN 62366-1

DIN EN 62366-1:2017

DIN EN 61326-1:2013

DIN EN 55011:2009 + A1:2010

IEC 61010-1:2010, AMD1:2016

IEC 61010-2-101:2015

IEC 61010-1:2010

Directive 2011/65/EU RoHS III

(incl. (EU) 2015/863 - DIN EN IEC 63000

QM-Systems in accordance with (EU) 2017/746 art.10(8)

Applied standard procedure: EN ISO 13485:2021

Ort und Datum der Unterzeichnung:

Neufahrn, 2022-06-21

Place and date of issue:


Matthias Dieckmann
General Manager




Christian Hötzel
Verantwortliche Person / PRRC



Quality Management

We are certified

Voluntary participation in regular monitoring according to ISO 9001:2008



TECO

MEDICAL INSTRUMENTS
PRODUCTION+TRADING GMBH

Dieselstraße 1

D-84088 Neufahrn N.B.

fon: +49-8773/707 80-0

fax: +49-8773/707 80-29

CERTIFICATE

for: **Mr. Vitalie Goreacii**

Company: **Sanmedico SRL**
Str. Petricani 88/1, oficiul 10
Chisinau - Rep. Moldova MD-2059
MOLDOVA

have participated with success at the intensive training session:

Application and technical training for following instruments:

- **Coatron X series**
 - **Installation**
 - **Application**
 - **General use, also in combination with TECAM Software**
 - **Technical and After Sales Service**

Supervisors: **Mr. Chr. Hoetzi and Mrs. Wendy Guo**

Place of Training: **TECO – Germany**

Date: **November 18th, 2019**


Christian Hoetzi
General Manager