ISO 9001:2008 DEKRA Certification DEKRA certified

Quality Management

We are certified

Voluntary participation in regular monitoring according to ISO 9001:2008

Quality Management EN ISO 13485 www.dekra-usa.com DEKRA certified

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

TO WHOM IT MAY CONCERN
To any governmental departments,
registration and/or trade offices
in Moldova

Distribution / Service Authorisation for the years 2019 - 2023

This letter confirms that company

SANMEDICO SRL
Str. Petricani 88/1, oficiul 10
Chisinau - Rep. Moldava MD-2059
MOLDOVA
Phone: 00373-22-623032
Email: sanmedico.office@gmail.com

is the **authorized, exclusive and sole** representative of **TECO Medical Instruments, Production + Trading GmbH, Dieselstrasse 1, 84088 Neufahrn i.NB, Germany**, for the territory of **Moldova,** only for all TECO products listed below. **Sanmedico** may participate in public and privat tenders, providing sales to all TECO customers in the territory. We as manufacturer, certify that our **warranty and service** 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.

Validity: August 20th, 2019 to December 31st, 2023

Termination: Confirmation ends automatically on Dec. 31st of 2023 and must be then renewed.

TECO products:

- Coatron X (Eco, Pro, Top) new manual Coagulometers (1, 2 and 4 channel)
- Coatron A4, A6, A6 Plus Fully automated Coagulometers (4 and 6 channel)
- Complete line of Hemostasis Reagents, Consumables and Spareparts

This document is signed in Neufahrn, Germany, on August 20th, 2019.

TECO Medical Instruments, Production + Trading GmbH

TECO MEDICAL INSTRUMENTS PRODUCTION+TRADING GMBH Dieselstraße 1 D-84088 Neufahrn N.B. fon: +49-8773/70780-0

Christian Hoetzl
General Manager

Digitally signed by Monastîrschii Viorica
Date: 2022.03.21 14:09:13 EET
Reason: MoldSign Signature
Location: Moldova

KONFORMITÄTSERKLÄRUNG

DECLARATION OF CONFORMITY

Doc#022/06-2014

Wir / *We*

TECO Medical Instruments Production and Trading GmbH
Name des Herstellers / Manufacturer's *name*
Dieselstrasse 1, D-84088 Neufahrn NB
Anschrift / *Address*

erklären in alleiniger Verantwortung, dass unsere im beigefügten Anhang (2 Seiten) spezifizierten Produkte wie folgt gemäß der Richtlinie für In-vitro-Diagnostika Medizinprodukte 98/79/EC klassifiziert sind:
declare under our own responsibility, that our products specified in the enclosed addendum (2 pages) classified as follows according to the directive on in vitro diagnostic medical devices 98/79/EC:

Übrige Produkte – Reagenzien für In-vitro-Diagnostika
Other Products – Reagents for in vitro diagnostic

Allen anwendbaren Anforderungen der folgenden Richtlinien entsprechen:	*Meet all applicable requirements of:*
Richtlinie 98/79/EG über In-vitro-Diagnostika klassifiziert gemäß Artikel 9 als "alle anderen Produkte"	*Directive 98/79/EC on in-vitro-diagnostic medical devices classified according to article 9 as „all other products"*

Das QM-System des Herstellers ist zertifiziert nach:	*The QM-system of the manufacturer is certified for:*
EN ISO 13485:2016	***EN ISO 13485:2016***
Die vorstehende Konformitätserklärung ist gültig für alle Chargen dieser Produkte, die nach dem Datum der Unterzeichnung in Verkehr gebracht wurden.	*The above mentioned declaration of conformity is valid for all lots of this product, which are distributed after the date of signature.*
Konformitätsbewertungsverfahren:	*Conformity assessment procedure:*
Gemäß Anhang III der Richtlinie 98/79/EG	*According to Annex III of Directive 98/79/EC*

Ort und Datum der Unterzeichnung: Neufahrn, 26.03.2019
Place and date of issue: Neufahrn, March 26, 2019

Christian Hötzl
General Manager

Medical Instruments TECO Production+Trading GmbH

KONFORMITÄTSERKLÄRUNG – DECLARATION OF CONFORMITY

Übrige Produkte – Reagenzien für In-vitro-Diagnostika
Other products – Reagents for in vitro diagnostic

PT		
A0230-010	TEClot PT-S	5x2ml
A0230-040	TEClot PT-S	10x4ml
A0230-100	TEClot PT-S	10x10ml
A0260-020	TEClot PT-B Kit-20	Kit
A0260-050	TEClot PT-B Kit-50	Kit
PTT		
A0300-025	TEClot APTT-S, Kt-25	Kit
A0300-050	TEClot APTT-S, Kit-50	Kit
A0320-050	TEClot APTT-S	10x5ml
A0320-100	TEClot APTT-S	10x10ml
A0350-050	CaCl2, 0,025M	10x5ml
A0350-100	CaCl2, 0,025M	10x10ml
Fibrinogen		
A0501-010	TEClot FIB Kit-10	5x2ml
A0501-025	TEClot FIB Kit-25	5x5ml
A0511-020	TEClot FIB	10x2ml
A0511-050	TEClot FIB	10x5ml
A0590-125	IBS Buffer	1x125ml
TT		
A0401-020	TEClot TT	10x2ml
Protein S		
A0600-002	TEClot PS Kit	Kit
Lupus Anticoagulant		
A0700-020	TEClot LA Screen	10x2ml
A0800-010	TEClot LA Confirm	10x1ml
Factor V Leiden		
A0900-004	TEClot PCA Ratio Kit	Kit
Chromogenic Tests		
C1000-010	TEChrom AT (anti-Xa) Kit-10	Kit
C1010-020	TEChrom AT (anti-Xa) liquid	Kit
C1100-012	TEChrom PC Kit	Kit
Semiquantitative D-Dimer		
D2050-000	D-Dimer Agglutination Kit	Kit

KONFORMITÄTSERKLÄRUNG – DECLARATION OF CONFORMITY

Übrige Produkte – Reagenzien für In-vitro-Diagnostika
Other products – Reagents for in vitro diagnostic

Quantitative D-Dimer		
D2000-002	Dimex D-Dimer Kit-50	Kit
D2000-005	Dimex D-Dimer Kit-100	Kit
D2010-012	Red D-Dimer Kit	Kit
D2020-005	Blue D-Dimer LC Kit-65	Kit
D2020-010	Blue D-Dimer LC Kit-130	Kit
Control Plasma		
P6001-010	Tecontrol N	10x1ml
P6101-010	Tecontrol A	10x1ml
P6201-010	Tecontrol A+	10x1ml
P7100-005	TEControl LA positive	5x1ml
Reference Plasma		
P8001-010	TECal N	10x1ml
P8200-005	TECal DD	5x1ml
Deficient Plasma		
P5001-010	Deficient Plasma II	10x1ml
P5101-010	Deficient Plasma V	10x1ml
P5201-010	Deficient Plasma VII	10x1ml
P5301-010	Deficient Plasma VIII	10x1ml
P5401-010	Deficient Plasma IX	10x1ml
P5501-010	Deficient Plasma X	10x1ml
P5601-010	Deficient Plasma XI	10x1ml
P5701-010	Deficient Plasma XII	10x1ml

CERTIFICATE

TECO

EN ISO 13485:2016

DEKRA Certification GmbH hereby certifies that the organization

TECO Medical Instruments, Production + Trading GmbH

Scope of certification:

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

Certified location:

Dieselstraße 1, 84088 Neufahrn, Germany

has established and maintains a quality management system according to the above mentioned standard. The conformity was adduced with audit report no. 50788-Z5-00.

Certificate registration no.:	50788-14-01	Certificate valid from:	2019-05-31
Validity of previous certificate:	2019-05-30	Certificate valid to:	2022-05-30

DEKRA Certification GmbH Stuttgart, Handwerkstraße 15 • D-70565 Stuttgart

DEKRA Certification

DAkkS Deutsche Akkreditierungsstelle D-ZM-16029-08-00

Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2019-05-31

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Neufahrn, 26/04/2018

TO WHOM IT MAY CONCERN

We confirm that the instruments Coatron X Eco, Coatron X Pro and Coatron X Top have a closed cuvette system. Cuvettes have to be purchased with voucher identification code from TECO GmbH.

Medical Instruments
TECO
Production+Trading GmbH

Christian Hoetzl
General Manager
TECO Germany

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Quality Management

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Quality Management EN ISO 13485 www.dekra-iasl.com DEKRA certified

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CERTIFICATE

for: **Mr. Vitalie Goreacii**

Company: **Sanmedico SRL**
Str. Petricani 88/1, oficiul 10
Chisinau - Rep. Moldava 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. Hoetzl and Mrs. Wendy Guo

Place of Training: TECO – Germany

Date: November 18th, 2019

Christian Hoetzl
General Manager