CE

KONFORMITÄTSERKLÄRUNG

DECLARATION OF CONFORMITY

Doc#001/12-2020

Wir / *We* **TECO Medical Instruments Production and Trading GmbH**
Name des Herstellers / Manufacturer's *name*
Dieselstrasse 1, 84088 Neufahrn, Germany
Anschrift / *Address*

erklären in alleiniger Verantwortung, dass die Produkte – IVD-Blutgerinnungsmessgeräte,
declare under our own responsibility, that the products – IVD Coagulation analyzers

Coatron X Eco, Pro, Top

Bezeichnung, Typ oder Modellname / *name, type or model*

Alle anwendbaren Anforderungen der folgenden Richtlinien entsprechen:

1. Richtlinie 98/79/EG über In-vitro Diagnostika klassifiziert gemäß Artikel 9 –"alle anderen Produkte" Anhang II – Liste A

2. Richtlinie 2014/30/EU über Elektromagnetische Verträglichkeit

3. Richtlinie 2011/65/EU RoHS II

Standards and regulations applied:

1. Directive 98/79/EC on In-vitro diagnostic medical devices classified according to article 9 as: "all other products" Annex II – list A

2. Directive 2014/30/EU on electromagnetic Compatibility

3. Directive 2011/65/EU RoHS II

Weitere angewandte Normen:

4. Sicherheit:	EN 61010-2-101:2015
5. Risikomanagement:	DIN EN ISO 14971:2013-04
6. Informationen:	EN ISO 18113-3:2011
7. Medizingeräte-Software - Lebenszyklus-Prozesse:	DIN EN 62304:2016

Further related standards:

4. Safety:	*EN 61010-2-101:2015*
5. Risikmanagement:	*DIN EN ISO 14971:2013-04*
6. Information:	*EN ISO 18113-3:2011*
7. Medical device software - life-cycle processes:	*DIN EN 62304:2016*

Das QM-System des Herstellers ist zertifiziert nach:

EN ISO 13485:2016

The QM-system of the manufacturer is certified for:

EN ISO 13485:2016

Konformitätsbewertungsverfahren:

Gemäß Anhang III der Richtlinie 98/79/EG

Conformity assessment procedure:

According to Annex III of Directive 98/79/EC

Ort und Datum der Unterzeichnung: Neufahrn, 08.12.2020
Place and date of issue: Neufahrn, December 8, 2020

Digitally signed by Monastîrschii Viorica
Date: 2022.09.14 10:59:40 EEST
Reason: MoldSign Signature
Location: Moldova

Matthias Dieckmann
General Manager

Medical Instruments TECO Production+Trading GmbH

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

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

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 and Agreement for the year 2020 to 2022

This letter confirms that **Sanmedico**
Mun. Chisinau
Str. Petricani 88/1 of. 10
Republica MOLDOVA

is the legal representative of **TECO Medical Instruments Production + Trading GmbH, Dieselstr. 1, 84088 Neufahrn i. NB, Germany,** for the territory of **MOLDOVA** only for all TECO products listed below. **Sanmedico** may register medical equipment and reagents into the Registry of medical equipment of MOLDOVA and 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.
TECO authorizes Sanmedico to register the product on behalf of TECO.
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:	September 14th, 2020 to December 31st, 2022
Termination:	Confirmation ends automatically on Dec. 31st of 2022

Please Note: Fixed-term Authorization Letter terminate automatically if they are not renewed.

TECO products:

- Coatron X Eco — Manual 1-channel coagulometer
- Coatron X Pro — Manual 2-channel coagulometer
- Coatron X Top — Manual 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 September 14, 2020

The legal representative of
TECO Medical Instruments, Production + Trading GmbH

Christian Hoetzl

Medical Instruments TECO Production+Trading GmbH

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-iasl.com DEKRA certified

TECO

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PRODUCTION+TRADING GMBH

Dieselstraße 1
D-84088 Neufahrn N.B.
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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