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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 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 Decamber 3th, 2024

TECO Medical Instruments Production+Trading GmbH

Christian Hoetzl
General Management

20-0104 • DSK Bayerbach • Ø 08774/96030

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:
Place and date of issue: Neufahrn, 2022-06-21

Matthias Dieckmann
General Manager

Medical Instruments TECO Production+Trading GmbH

Christian Hötzl
Verantwortliche Person / PRRC

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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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

18 0250 • DSK Bayerbach • ☎ 08774/9603-0

Current issue date:	10 November 2022	Original approval(s):
Expiry date:	9 November 2025	ISO 13485 - 10 November 2022
Certificate identity number:	10479697	

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

UKAS MANAGEMENT SYSTEMS 0001

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