



Quality Management

We are certified

Voluntary participation in regular monitoring according to ISO 9001:2008



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



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

Christian Hoetzl
General Manager



KONFORMITÄTSERKLÄRUNG

DECLARATION OF CONFORMITY

Doc#100/07-2021

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 unten gelisteten IVD Zubehör Produkte:
declare under our own responsibility, that the IVD accessories products, listed below:

Doppelküvette / <i>Double cuvette</i>	Ref. 19 000 02
Einzelküvette / <i>Single cuvette</i>	Ref. 20 000 02, 24 100 00
4-fach Küvette / <i>Cuvette 4 pos/ea</i>	Ref. 80 521 10
6-fach Küvette / <i>Cuvette 6 pos/ea</i>	Ref. 80 560 00
6-fach Küvette (micro) / <i>Cuvette 6 pos/ea (micro)</i>	Ref. 80 570 00

allen anwendbaren Anforderungen folgender Richtlinien entsprechen: *meet all applicable requirements of:*

1. Richtlinie 98/79/EG über In-vitro Diagnostika und ihrem Zubehör, klassifiziert gemäß Artikel 9 als: "alle anderen Produkte"- im Sinne von Zubehör zu In vitro Diagnostika gemäß Artikel 1.

1. Directive 98/79/EC on In-vitro diagnostic medical devices and their accessories, classified according to article 9 as: "all other products" – and in term of accessories for in vitro diagnostics according to article 1.

2. Richtlinie 2011/65/EU (RoHS III)

2. Directive 2011/65/EU (RoHS III)

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

Konformitätsbewertungsverfahren gemäß:

Conformity assessment procedure according to:

Gemäß Anhang III der Richtlinie 98/79/EG

According to Annex III of Directive 98/79/EC

Ort und Datum der Unterzeichnung:
Place and date of issue:

Neufahrn, 27.07.2021
Neufahrn, July 27, 2021

Matthias Dieckmann
General Manager





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:

EN ISO 13485:2016

The QM-system of the manufacturer is certified for:

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:
Place and date of issue:

Neufahrn, 26.03.2019
Neufahrn, March 26, 2019


Christian Hötzel
General Manager



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	CaCl ₂ , 0,025M	10x5ml
A0350-100	CaCl ₂ , 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 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



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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

TECO

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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.



Christian Hoetzel
General Manager
TECO Germany



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Voluntary participation in regular monitoring according to ISO 9001:2008



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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



Important Customer Information regarding the introduction of the IVDR

Due to coming regulation 2017/746 (IVDR), which will apply from May 26th, Teco has classified their products new.

1. Sales of consumables from 2022/05/26

Cuvettes (for Coatron M, X, A Family) REF: 2410000 2420000 2000002 1900002 8052110 8056000 8057000 Rinse and Clean solution (for Coatron A Family) REF: 2150001 2150000 2150009 2151009	Classified as: Generic laboratory product (IVDR, Art. 1, Para 3a)
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On May 2022, Teco had withdrawn cuvettes, rinses and cleaners from EU registration for IVD and offer these products as general laboratory products without CE mark! Of course, the premium quality, safety and performance remains unchanged.

2. Sales of auxiliary reagents from 2022/05/26

Buffers and solutions REF: A0350-050 Calcium Chloride 0.025M REF: A0590-125 IBS Buffer REF: A0592-100 Owren's Buffer REF: A0593-035 Dilution Buffer	Classified as: Generic laboratory product, chemical solution (IVDR, Art. 1, Para 3a)
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On May 2022, Teco had withdrawn these auxiliary reagents from EU registration for IVD and offer these products only in conformity to REACH regulation EG/1907/2006.

3. Sales of Coatron X family from 2022/05/26

Coatron X Family REF: 8110110 8110120 8110140 85001 85002 85004 8080000 8070000 8042000 9830021 9830022 9830024 8111510 8111520 8111540 8090000 8090008 8092000 8092040 8092060 8092061	Classified as: Class A (IVDR) (IVDR, Annex VIII, rules 5b)
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Since May 2022, TECO offers the Coatron X family in conformity to IVDR, Class A.



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4. Sales of Coatron A family from 2022/05/26

On May 2022, Teco had withdrawn the Coatron A family from EU registration for IVD, but we will still distribute the instruments as 'old device'* in Europe. Consumables, spare parts and service will be available beyond May 26, 2022 for at least 10 years.

* Old devices are those devices that were placed on the market or put into service before 26 May 2022 in accordance with the IVDD or the applicable national rules before the IVDD had become applicable and which are still on the market or in use after 26 May 2022." (guidance MDCG 2022-8)

5. Sales of reagents/plasma intended for clotting, chromogenic or immunological test

Due to postponement of IVDR (EU) 2017/746 for Class B/C devices to 26 May 2026/2027 , Teco will offer these IVD-products only in conformity with old IVDD 98/79/EC.

6. New prices

In March 15 2022 we adjusted our prices, because of increased production costs in consequence of Covid-19 pandemic. Now the ongoing war in Ukraine worsened the market situation again. Disrupted supply chains and hyperinflation on energy forces us again to plan further price increase of 10-15% planned for 2023. In addition, we recommend very early forecasts. Orders without forecasts may take 6 months or longer, due to extreme delay time for some components or raw material.

Best regards

Neufahrn, September 28th 2022

Matthias Dieckmann,
General Manager