



# 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



# 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

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

# 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



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

DEKRA Certification GmbH \* Handwerkstraße 15 \* D-70565 Stuttgart \* [www.dekra-certification.de](http://www.dekra-certification.de)



Deutsche  
Akkreditierungsstelle  
D-ZM-16029-08-00



Quality Management

We are certified

Voluntary participation in regular monitoring according to ISO 9001:2008



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## 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. Moldova 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 20<sup>th</sup>, 2019 to December 31<sup>st</sup>, 2023

Termination:

Confirmation ends automatically on Dec. 31<sup>st</sup> 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 20<sup>th</sup>, 2019.

TECO Medical Instruments, Production + Trading GmbH



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Christian Hoetzl  
General Manager