Quality Management
We are certified

Quality Management

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 Moldava

Distribution / Service Authorisation for the year 2018 / 2019

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 an **authorized** representative of **TECO Medical Instruments, Production + Trading GmbH, Dieselstrasse 1, 84088 Neufahrn i.NB, Germany**, for the territory of **Moldava**, 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: January 1st 2018 to December 31st, 2019

Termination: Confirmation ends automatically on Dec. 31st of 2019 and must be then renewed.

TECO products:

- Coatron 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 January 29th, 2018.

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

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Dieselstraße 1
D-84088 Neufahrn N.B.
fon: +49-8773/70780-0

Christian Hoetzl

Digitally signed by Rodnitchii Andrei
Date: 2019.03.20 11:23:48 EET
Reason: MoldSign Signature
Location: Moldova

CE

KONFORMITÄTSERKLÄRUNG

DECLARATION OF CONFORMITY

Doc#001/35-2014

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*

allen anwendbaren Anforderungen der folgenden Richtlinien entsprechen:	*meet all applicable requirements of:*
1. Richtlinie 98/79/EG über In-vitro Diagnostika klassifiziert gemäß Artikel 9 als: "alle anderen Produkte"	*1. Directive 98/79/EC on In-vitro diagnostic medical devices classified according to article 9 as: "all other products"*
2. Richtlinie 2014/30/EU über Elektromagnetische Verträglichkeit	*2. Directive 2014/30/EU on electromagnetic Compatibility*
3. Richtlinie 2011/65/EU RoHS II	*3. Directive 2011/65/EU RoHS II*
4. Richtlinie 2014/35/EU Niederspannungsrichtlinie	*4. Directive 2014/35/EU Low Voltage*
Das QM-System des Herstellers ist zertifiziert nach:	*The QM-system of the manufacturer is certified for:*
EN ISO 13485:2012+AC:2012	***EN ISO 13485:2012+AC:2012***

Diese Erklärung bescheinigt die Übereinstimmung mit den genannten Harmonisierungsrechtsvorschriften, beinhaltet jedoch keine Zusicherung von Eigenschaften.

This declaration attests the accordance with the mentioned harmonization rule but does not include a warranty of properties.

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, 14.03.2018
Neufahrn, March 14, 2018

Christian Hötzl
General Manager

Medical Instruments TECO Production+Trading GmbH

Gültig bis 01.04.2019
Valid until April 1st, 2019

CERTIFICATE

TECO

EN ISO 9001:2008

DEKRA Certification GmbH hereby certifies that the company

TECO Medical Instruments, Production + Trading GmbH

Scope of certification:

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

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-Z4-00.

This certificate is valid from 2016-05-31 to 2018-09-14

Certificate registration no.: 50788-56-02

DEKRA Certification GmbH Stuttgart, 2016-05-24

CERTIFICATE

TECO

EN ISO 13485:2012 + AC:2012

DEKRA Certification GmbH hereby certifies that the company

TECO Medical Instruments, Production + Trading GmbH

Scope of certification:

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

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-Z4-00.

This certificate is valid from 2016-05-31 to 2019-05-30

Certificate registration no.: 50788-11-00

DEKRA Certification GmbH Stuttgart; 2016-05-24

DEKRA Certification GmbH * Handwerkstraße 15 * D-70565 Stuttgart * www.dekra-certification.de

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

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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