CE

KONFORMITÄTSERKLÄRUNG

DECLARATION OF CONFORMITY

Doc#006/05-2014

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 das Produkt – IVD-Blutgerinnungsmessgerät,
declare under our own responsibility, that the product – IVD Coagulation analyzer

Coatron A4

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

allen anwendbaren Anforderungen der folgenden Richtlinien entspricht:	*meets 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*
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***
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: Neufahrn, 27.03.2019
Place and date of issue: Neufahrn, March 27, 2019

Christian Hötzl
General Manager

Digitally signed by Monastîrschii Viorica
Date: 2022.10.21 10:46:09 EEST
Reason: MoldSign Signature
Location: Moldova

Medical Instruments TECO Production+Trading GmbH

TECO
MEDICAL INSTRUMENTS, PRODUCTION + TRADING GMBH
Web: www.teco-gmbh.com
Email: info@teco-gmbh.com

DIESELSTRASSE 1
D-84088 NEUFAHRN NB
fon: #49 8773 70780 00
fax: #49 8773 70780 29

CERTIFICATE OF PERFORMANCE

	Coatron A4 1.07.04a	**Coatron A6** 1.03.04a	**Coatron A6 Plus** 1.03.05a
Throughput samples/h [1], [2]			
PT	156	194	320
aPTT (INC=120s)	90	125	160
TT	110	182	320
FIB	100	148	250
DD	88	108	210
FDP	66	108	148
PT+aPTT+Fib Clean=MIN Mode=BAT Clean=MAX Mode=BAT Clean=MAX Mode=ECO	 35 28 23	 50 35 30	 80 60 45
PT+aPTT+Fib+TT	27	39	61
PT+aPTT+Fib+TT+DD	21	29	47
PT+aPTT+Fib+TT+DD+FDP	16	23	38
Consumption of rinse tank 1.25l [1]			
best case [2] Mode=BAT [3] Mode=ECO [3]	1800 tests 1100 tests 1600 tests	2200 tests 1300 tests 1800 tests	3000 tests 1800 tests 2200 tests
total volume in cuvette	150µL	75µL	72µL
Performance	precision C.V.	linearity of calibration	linear range
PT (s)	0.83%	-	5 – 600
aPTT (s)	2,76%	-	5 – 600
FIB (mg/dl)	2,73%	0,995	50 – 600
DD (ng/mL)	5,00%	0,99	50 – 3000
AT (%)	3,20%	0,998	15 – 125
interfering substances			
Hemoglobin	9.00 g/l	9.00 g/l	9.00 g/l
Bilirubin	40 mg/dl	40 mg/dl	40 mg/dl
Triglyceride	2500 mg/dl	2500 mg/dl	2500 mg/dl

[1] real clinical data depending strongly on the workflow and samples per run and can be 50% lower as assigned or even more

[2] running fully loaded patient racks with test PT only in mode BAT and Clean=MIN

[3] running 10samples with PT+aPTT+FIB in random access in CLEAN=MAX

13th March 2018

Christian Baumgartner
Research department of TECO GmbH

Christian Baumgartner
I am approving this document
2018-03-13 17:58:26

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:	*The QM-system of the manufacturer is certified for:*
EN ISO 13485:2016	***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: Neufahrn, 26.03.2019
Place and date of issue: Neufahrn, March 26, 2019

Christian Hötzl
General Manager

Medical Instruments TECO Production+Trading GmbH

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	CaCl2, 0,025M	10x5ml
A0350-100	CaCl2, 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

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
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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

MEDICAL INSTRUMENTS
PRODUCTION+TRADING GMBH

Dieselstraße 1
D-84088 Neufahrn N.B.
fon: +49-8773/707 80-0
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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