



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 *Meet all applicable requirements of:*
entsprechen:

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 Hötzl
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

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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



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

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



TECO

MEDICAL INSTRUMENTS
PRODUCTION+TRADING GMBH

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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 Hoetzl
General Manager
TECO Germany