



# 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

|                                 |                             |         |
|---------------------------------|-----------------------------|---------|
| <b>PT</b>                       |                             |         |
| 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     |
| <b>PTT</b>                      |                             |         |
| 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 <sub>2</sub> , 0,025M  | 10x5ml  |
| A0350-100                       | CaCl <sub>2</sub> , 0,025M  | 10x10ml |
| <b>Fibrinogen</b>               |                             |         |
| 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 |
| <b>TT</b>                       |                             |         |
| A0401-020                       | TEClot TT                   | 10x2ml  |
| <b>Protein S</b>                |                             |         |
| A0600-002                       | TEClot PS Kit               | Kit     |
| <b>Lupus Anticoagulant</b>      |                             |         |
| A0700-020                       | TEClot LA Screen            | 10x2ml  |
| A0800-010                       | TEClot LA Confirm           | 10x1ml  |
| <b>Factor V Leiden</b>          |                             |         |
| A0900-004                       | TEClot PCA Ratio Kit        | Kit     |
| <b>Chromogenic Tests</b>        |                             |         |
| C1000-010                       | TEChrom AT (anti-Xa) Kit-10 | Kit     |
| C1010-020                       | TEChrom AT (anti-Xa) liquid | Kit     |
| C1100-012                       | TEChrom PC Kit              | Kit     |
| <b>Semiquantitative D-Dimer</b> |                             |         |
| 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

|                             |                         |        |
|-----------------------------|-------------------------|--------|
| <b>Quantitative D-Dimer</b> |                         |        |
| 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    |
| <b>Control Plasma</b>       |                         |        |
| P6001-010                   | Tecontrol N             | 10x1ml |
| P6101-010                   | Tecontrol A             | 10x1ml |
| P6201-010                   | Tecontrol A+            | 10x1ml |
| P7100-005                   | TEControl LA positive   | 5x1ml  |
| <b>Reference Plasma</b>     |                         |        |
| P8001-010                   | TECal N                 | 10x1ml |
| P8200-005                   | TECal DD                | 5x1ml  |
| <b>Deficient Plasma</b>     |                         |        |
| 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



Deutsche  
Akkreditierungsstelle  
D-ZM-16029-08-00