Name and Address of Manufacturer (Legal & Actual Manufacturers if present)

TECO Medical Instruments Production + Trading GmbH
Dieselstrasse 1, D-84088 Neufahrn in Niederbayern, Germany

Product Name	TEClot TT
REF	A0401-020
Variants /Size /Components (Kit)	10x 2mL TT Reagent
EMDN	W0103020103
GMDN	55988
SRN/ARN (EU-REP)	SE-MF-000022201
GTIN	4260182785829
Basic UDI-DI	B-TT-A0401-0207P
Eudamed-ID	D-TT-A0401-0207P
Eudamed-DI	B-TT-A0401-0207P
HS./CT.No	3822.1900
Codes of IVD	IVR0608/ IVD4005/ IVP3005
Intended use	Screening of coagulation disorder, usually it is to confirm dysfibrinogenemia. TEClot TT reagent can be used manually or on semi-automated and automated instruments. The test is commonly applied to detect various sources of interference with normal blood coagulation. Prolongation of the thrombin clotting time can be taken as a qualitative indication of abnormal fibrinogen levels (high or low), or the presence of interfering substances such as FDP's or heparin. Quantitative evaluation of the possible causes of prolonged thrombin clotting time should be performed as follow-up studies, such as APTT or chromogenic assay for heparin, Clauss fibrinogen, FDP determinations,heparin neutralization by protamine sulphate or polybrene, normal plasma mixing studies or reptilase assay to distinguish between hypofibrinogenaemia and FDP effects.
Classification	IVDR , Class B, Rule-6
Regulation	(EU) 2017/746 (IVDR); 1907/2006/EG annex II (REACH), 1272/2008 (CLP) and 2020/878 (REACH, amendment). The TECO quality assurance is accordance to IVDR, REACH, CLP and complies to EN ISO 13485:2021.

*** STATEMENT ***

We hereby confirm that the above-listed products are in conformity with the following legislative acts:
Directive 98/79/EC on in vitro diagnostic medical devices, classified according to Article 9 as 'all other products'.

Quality assurance is in accordance with the requirements of Directive 98/79/EC on in vitro diagnostic medical devices for this category of products. The implemented quality management system complies with EN ISO 13485:2021.

All supporting documentation is retained under the control of the legal manufacturer.

Medical Instruments TECO Production+Trading GmbH

Signed by:
Wendy Guo 2026.06.24 11:31:10+02'00'
Wendy Guo
QC Department, TECO
PRRC (i.A.PM Reagenzien)