

 Medical Instruments Production + Trading GmbH	Technical File for IVD Product Registration	ND_A0320_DOC Rev2-2026-04-15 1(2)
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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 APTT-S
REF	A0320-050
Variants /Size /Components (Kit)	10x 5mL APTT Reagent
EMDN	W0103020102
GMDN	55982
SRN/ARN (EU-REP)	SE-MF-000022201
GTIN	4260182785355
Basic UDI-DI	B-APTTS-A0320-050AM
Eudamed-ID	D-APTTS-A0320-050AM
Eudamed-DI	B-APTTS-A0320-050AM
HS./CT.No	3822.1900
Codes of IVD	IVR0608/ IVD4005/ IVP3005
Intended use	Screening of coagulation disorder, monitoring Heparin Clotting test for quantitative determination of the Activated Partial Thromboplastin Time (APTT) in citrated human plasma using silicate as contact activator for factor XII. Intended to be used by professional laboratory personnel using coagulation analysers. The determination of the APTT is used for the global evaluation of the intrinsic pathway and detecting deficiencies of the intrinsic coagulation factors VIII, IX, XI, XII, and Fletcher Factor or other coagulation methods where an APTT reagent is required.
Classification	IVDR , Class C, Rule-3j
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.



PRRC (i.A.PM Reagenzien)