

 Medical Instruments Production + Trading GmbH	Technical File for IVD Product Registration	ND_A0260_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 PT-B
REF	A0260-050
Variants /Size /Components (Kit)	10x10mL PT-B Reagent, 5x5mL Diluent 5x5mL CaCl ₂ 0,025M
EMDN	W0103020801
GMDN	55986
SRN/ARN (EU-REP)	SE-MF-000022201
GTIN	4260182785218
Basic UDI-DI	B-PTB-A0260-050G2
Eudamed-ID	D-PTB-A0260-050G2
Eudamed-DI	B-PTB-A0260-050G2
HS./CT.No	3822.1900
Codes of IVD	IVR0608/ IVD4005/ IVP3005
Intended use	Screening of coagulation disorder, monitoring VKA (e.g. coumarins) TECLOT PT-B is used for the determination of INR value and prothrombin complex-activity (%-value) in whole blood according to Owren. It is ideal for monitoring of oral anticoagulation with vitamin-K inhibitors like Warfarin or Marcumar. PT according to Owren measures the combined activity of the vitamin-K dependent coagulation factors II, VII and X. In analysis, the sample is mixed with thromboplastin, CaCl ₂ , fibrinogen and coagulation factor V. TECLOT PT-B is not intended for selftesting.
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)