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-S		
REF	A0230-010	A0230-040	A0230-100
Variants /Size /Components (Kit)	5x 2mL PT Reagent	10x 4mL PT Reagent	10x 10mL PT Reagent
EMDN	W0103020101		
GMDN	30539		
SRN/ARN (EU-REP)	BE-AR-000000106		
GTIN	4260182785058	4260182785065	4260182785072
Basic UDI-DI	B-PTS-A0230-010WW	B-PTS-A0230-040X7	B-PTS-A0230-100WY
Eudamed-ID	D-PTS-A0230-010WW	D-PTS-A0230-040X7	D-PTS-A0230-100WY
Eudamed-DI	B-PTS-A0230-010WW	B-PTS-A0230-040X7	B-PTS-A0230-100WY
HS./CT.No	3822.1900		
Codes of IVD	IVR0608/ IVD4005/ IVP3005		
Intended use	Screening of coagulation disorder, monitoring VKA (e.g. coumarins) Clotting test for the quantitative determination of prothrombin time (PT) in citrated human plasma according to Quick. Intended to be used by professional laboratory personnel using coagulation analysers.		
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.

Medical Instruments TECO Production+Trading GmbH

Signed by:
Wendy Guo 2026.06.24 11:27:32+02'00'
Wendy Guo
QC Department, TECO
PRRC (i.A.PM Reagenzien)