

 Medical Instruments Production + Trading GmbH	Technical File for IVD Product Registration	ND_P8001_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	TECal N
REF	P8001-005
Variants /Size /Components (Kit)	5x1ml TECal N
EMDN	W0103020701
GMDN	45786
SRN/ARN (EU-REP)	SE-MF-000022201
GTIN	4260182787533
Basic UDI-DI	B-CAL-P8001-005X8
Eudamed-ID	D-CAL-P8001-005X8
Eudamed-DI	B-CAL-P8001-005X8
HS./CT.No	3822.9000
Codes of IVD	IVR0604/ IVD4005/ IVP3005/ IVS1006
Intended use	Use as a calibrator or normal control for following coagulation tests: PT, APTT, Thrombintime, Fibrinogen, Factors: II, V, VII, VIII, IX, X, XI, XII, Antithrombin, Protein-C, free Protein-S, D-Dimer
Classification	IVDR , Class C, Rule-3j, implementing Rule 1.5
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)