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	TEControl A Plus
REF	P6201-010
Variants /Size /Components (Kit)	10x1ml TEControl A Plus
EMDN	W0103020702
GMDN	30590
SRN/ARN (EU-REP)	SE-MF-000022201
GTIN	4260182787427
Basic UDI-DI	B-CTRL-P6201-010J9
Eudamed-ID	D-CTRL-P6201-010J9
Eudamed-DI	B-CTRL-P6201-010J9
HS./CT.No	3822.9000
Codes of IVD	IVR0604/ IVD4005/ IVP3005/ IVS1007
Intended use	Use as an abnormal control plasma 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.

Medical Instruments TECO Production+Trading GmbH

Signed by:
Wendy Guo 2026.06.24 11:48:31+02'00'
Wendy Guo
QC Department, TECO
PRRC (i.A.PM Reagenzien)