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	TEChrom AT (anti-Xa) liquid
REF	C1010-020
Variants /Size /Components (Kit)	6X6 mL FXa Reagent 3X3 mL Substrate
EMDN	W0103020602
GMDN	56156
SRN/ARN (EU-REP)	SE-MF-000022201
GTIN	4260182786161
Basic UDI-DI	B-AT-C-1010-020HL
Eudamed-ID	D-AT-C1010-020HL
Eudamed-DI	B-AT-C-1010-020HL
HS./CT.No	3822.1900
Codes of IVD	IVR0608/ IVD4005/ IVP3005
Intended use	Thrombophilia diagnosis / deficiency detection like AT deficiency caused by liver disease, malignancy, medication The TEChrom AT is intended for the quantitative determination of Antithrombin (AT) activity in human citrated plasma by chromogenic assay. AT is a major inhibitor of blood coagulation, acting to inhibit plasma serine proteases including factors IXa, Xa, Xla, and thrombin. The rate of the inhibition is significantly increased in the presence of heparin. AT deficiency may be congenital or acquired and is associated with an increased risk for thrombosis. Deficiencies may occur in liver disease, disseminated intravascular coagulation (DIC), septicaemia, pulmonary embolism, nephrotic syndrome, stroke, and thrombophlebitis. Most functional assays for AT rely on the ability of plasma to inactivate thrombin in the presence of heparin, such as the assay described by Odegard et al. More recently, it has been shown that a method based on the ability of plasma to inhibit factor Xa in the presence of heparin may be more accurate, since it eliminates interference due to heparin cofactor II which does not inhibit factor Xa.
Classification	IVDR , Class B, Rule-6
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 11:29:45+02'00'
Wendy Guo
QC Department, TECO
PRRC (i.A.PM Reagenzien)