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 FIB	
REF	A0511-020	A0511-050
Variants /Size /Components (Kit)	10x2mL FIB Reagent	10x5mL FIB Reagent
EMDN	W0103020201	
GMDN	55997	
SRN/ARN (EU-REP)	AT-MF-000024115	
GTIN	4260182785577	4260182785584
Basic UDI-DI	B-FIB-A0511-020N2	B-FIB-A0511-050NB
Eudamed-ID	D-FIB-A0511-020N2	D-FIB-A0511-050NB
Eudamed-DI	B-FIB-A0511-020N2	B-FIB-A0511-050NB
HS./CT.No	3822.1900	
Codes of IVD	IVR0608/ IVD4005/ IVP3005	
Intended use	Screening of fibrinogen disorder caused by liver disease, malignancy, medication The TEClot FIB is intended for the quantitative determination of fibrinogen in human plasma according to method developed by Clauss. Levels of fibrinogen can increase as a result of inflammation, pregnancy or oral contraceptive use. Decreased levels can be found in certain states such as liver disease and DIC. Congenital deficiencies include afibrinogenaemia (no detectable fibrinogen), hypofibrinogenaemia (<1 mg/ml) and dysfibrinogenaemia (abnormal fibrinogen molecule)	
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 11:30:30+02'00'
Wendy Guo
QC Department, TECO
PRRC (i.A.PM Reagenzien)