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	Red D-Dimer
REF	D2010-012
Variants /Size /Components (Kit)	3x4ml Latex 3x7ml Reaction Buffer
EMDN	W0103020503
GMDN	47349
SRN/ARN (EU-REP)	SE-MF-000022201
GTIN	4260182787113
Basic UDI-DI	B-DD-D2010-0126W
Eudamed-ID	D-DD-D2010-0126W
Eudamed-DI	B-DD-D2010-0126W
HS./CT.No	3822.1900
Codes of IVD	IVR0602/ IVD4005/ IVP3007
Intended use	Exclusion (diagnostic) of deep vein thrombosis (DVT) or pulmonary embolism (PE) Immunoturbidimetric reagent for the quantitative determination of D-Dimer concentration in human plasma on optical Coagulometer at 600-800nm.
Classification	IVDR , Class C, Rule-3k
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 11:29:00+02'00'
Wendy Guo
QC Department, TECO
PRRC (i.A.PM Reagenzien)