Name and Address of Manufacturer (Legal & Actual Manufacturers if present)

TECO Medical Instruments Production + Trading GmbH
Dieselstrasse 1, D-84088 Neufahrn in Niederbayern, Germany

Statement of legal liability

We hereby declare that the in-vitro diagnostic medical device

Product Name	TEClot PT-S
REF	A0230-040
EMDN	W0103020101
GMDN	30539
SRN/ARN (EU-REP)	BE-AR-000000106
GTIN	4260182785065
Eudamed-ID	D-PTS-A0230-040X7
Eudamed-DI	B-PTS-A0230-040X7
HS./CT.No	3822.1900
IVR Code	IVR0608
IVDR Classification	Class C, Rule-3j

is 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“.
The Quality Assurance is in accordance with the requirements of Directive 98/79/EC on in-vitro-diagnostic medical devices for those kind of products.The implemented QM Process complies with EN ISO 13485:2021.

and that all supporting documentation is retained under the control of the legal manufacturer.

Product Description

IVD Product List of Variants	A0230-040 10x 4mL
Intended use	Clotting test for the quantitative determination of prothrombin time (PT) in citrated human plasma according to Quick. Intended to be used by professional laboratory personnel using coagulation analysers. The determination of PT is used for the global evaluation of the extrinsic pathway of coagulation. Prolonged clotting times maybe observed in the following situations: deficiency or inhibition of extrinsic coagulation factors II,V,VII,X, Vitamin-K, Fibrinogen, presence of Vitamin-K inhibitors like Phenprocoumon, Warfarin or others.
IVD Kit Components	10 vials of 4mL PT reagent

(PRRC / VP)