EC declaration of conformity

The manufacture
InVivo BioTech Services GmbH
Neuendorfstr. 24a
16761 Hennigsdorf
Germany

here within declares that the product

Product name: Selenotest ELISA
Product version: 4
Intended use: Quantitative measuring of human selenoprotein P in serum
Product code: STE

conforms with the essential requirements and complies to the regulations of the
of 27 October 1998
on in vitro diagnostic medical devices

The product complies with the relevant and applicable national standards in the framework of the implementation of the harmonised standards under European Union harmonisation legislation published in the Official Journal of the European Union No. OJ C226 from 10.7.2015.

The product complies with the national legal requirements of the Chemicals Act, the Act on Medical Devices, the Biological Agents Ordinance and the Hazardous Substances Ordinance in their appropriate versions.

The product development, design and manufacture are based on expert group recommendations and applicable recommendations of the subsequent listed institutions in their appropriate versions: CLSI, EDMA, GHTF, ICH, MEDDEV, NB-MED.

A complete listing of the applied standards, legal requirements, guidelines and recommendations is part of the technical product documentation.

Berlin, 12th December 2016
Siegmund Karasch
CEO

Torsten Schulz
Responsible for documentation