CE

EC declaration of conformity

The manufacture

InVivo BioTech Services GmbH
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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
Directive 98/79/EC of the European Parliament and of the Council
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 theirs appropriate versions.

The product development, design and manufacture are based on expert group recommendations and applicable recommendations of the subsequent listed institutions in theirs 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
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Responsible for documentation