EC DECLARATION OF CONFORMITY

without the participation of an Authorized Person - diagnostic medical agents *in vitro*

According to Section 13 par. 2 of the Act No. 22/1997 Coll. on technical requirements for products and on changes and amendments to other Acts, in the wording of later regulations (below only the "Act") and according to the Council and European Parliament Directive 98/79/EC dated October 27, 1998, on *in vitro* diagnostic medical agents (below only "Council Directive 98/79/EC"), requirements of which were adopted in the Czech Government Order No. 453/2004 Coll. establishing technical requirements for *in vitro* diagnostic medical agents, in the wording of later regulations (below only Government Order No. 453/2004 Coll.).

Manufacturer:

GeneProof a.s., Vídeňská 119, 619 00 Brno

Hereby declares that the following product:

GeneProof Warfarin dose VKORC/CYP2C9 PCR Kit

is classified in category D, Other Medical Agents. The PCR kit is designed for the detection of polymorphisms in the sub-unit 1 of the vitamin K epoxide reductase enzyme complex encoded by the VKORC1 (1173C>T) gene and allelic variants of the CYP2C9*2 (430C>T) and CYP2C9*3 (1075A>C) genes encoding the P450 2C9 cytochrome by the real-time Polymerase Chain Reaction (PCR) method. **These polymorphisms significantly impact the genetic component of the individual sensitivity variability to warfarin. The kit includes an application for calculating genetic and non-genetic influences for the establishment of an optimum warfarin daily dose.** The kit is designed for *in vitro* diagnostics.

This product complies with the basic requirements of Annex No. 1 to the Government Order No. 453/2004 Coll. and under normal use it is safe for its intended purpose. The manufacturer has taken measures assuring compliance of all medical agents introduced into the market with their technical documentation and with the basic requirements.

The following act and directive were used to demonstrate the compliance:

- Europe parliament and Council directive 98/79/ES
- Goverment requlation No. 453/2004 Coll.

Procedure described in Annex No. 3 was used to evaluate the basic characteristics of the product by the designated method.

Brno on **April 8, 2014**

RNDr. Radek HORVÁTH Ph.D.
Quality Assurance/Quality Control department
Head of department
(Name, position and signature of the authorized person)

Manufacturer's stamp

GeneProof®
Molecular diagnostics for your routine
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