EC DECLARATION OF CONFORMITY

without the participation of an Notified body - diagnostic medical devices *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 devices (below only "Directive"), requirements of which were adopted in the Czech Government Order No. 453/2004 Coll. establishing technical requirements for *in vitro* diagnostic medical devices, in the wording of later regulations (below only Government Order No. 453/2004 Coll.).

MANUFACTURER

GeneProof a.s., Vídeňská 119, 619 00 Brno / www.geneproof.com

hereby declares that following product

GeneProof Factor V Leiden PCR Kit

is classified in category D, other Medical Agents. The PCR kit is designed for the detection of the G1691A mutation in the human factor V gene (Leiden mutation) by the real-time Polymerase Chain Reaction (PCR) method. This method is based on the PCR amplification of a DNA sequence bearing the Leiden mutation and on the hybridization of the amplified sequence with fluorophore marked probes for the standard G1691G allele and for the mutant A1691A allele of the human factor V gene. 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
- Government 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 June 19, 2014

RNDr. Miloš DENDIS
Research and development department
Head of department
(Name, position and signature of authorized person)

Manufacturer´s stamp:

GeneProof
Molecular diagnostics for your routine
GeneProof a.s. / Vídeňská 119, CZ-619 00 Brno
IČ/DIČ: CZ/26981947 / www.geneproof.com

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