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 MTHFR A1298C PCR Kit

is classified in category D, other medical devices. The PCR kit is designed for the detection of the A1298C mutation in the gene for methylentetrahydropholate reductase (MTHFR) by the real-time Polymerase Chain Reaction (PCR) method. This method is based on the PCR amplification of a DNA sequence for MTHFR bearing the A1298C mutation and on the hybridization of the amplified sequence with fluorophore labelled probes for the standard C1298C allele and for the mutant A1298A allele of the MTHFR 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 devices 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 January 28, 2015

RNDr. Radek HORVÁTH, Ph.D.
Quality Assurance/Quality Control depatment
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: CZ26981947 / www.geneproof.com

GeneProof
Molecular diagnostics for your routine