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, requirements of which were adopted in the Czech Government Order No. 56/2015 Coll. establishing technical requirements for *in vitro* diagnostic medical devices, in the wording of later regulations (below only Government regulation No. 56/2015 Coll.).

MANUFACTURER

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

hereby declares that following product

GeneProof PAI-1 Genotyping PCR Kit

is classified in other medical devices. The PCR kit is designed to detect polymorphism in promoter of *PAI* type 1 gene by the real-time polymerase Chain Reaction (PCR) method. Method is based on amplification and detection of target sequence using allele specific fluorophore labelled probes. Target sequence is insertion-deletion polymorphism 4G/5G. Presence of wild-type allele (5G/5G) is detected in FAM fluorescent channel and mutant allele (4G/4G) in HEX fluorescent channel. In case of heterozygous genotype (4G/5G) signal is detected in both channels. Detection kit contains Ready to Use MasterMix and utilizes "hot start"technology, minimizing non-specific reactions and assuring maximum sensitivity. Kit is designed for *in vitro* diagnostics.

This product complies with the basic requirements of Annex No. 1 to the Government Order No. 56/2015 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 regulation No. 56/2015 Coll.

Procedure described in Annex No. 3 Government Order No. 56/2015 Coll. was used to evaluate the basic characteristics of the product by the designated method.

Brno on September 3, 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
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