

**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 Directive 98/79/EC, requirements of which were adopted in the Government Order No. 453/2004 Coll. establishing technical requirements for diagnostic medical agents *in vitro*.

Manufacturer

GeneProof a.s., Viniční 235, 615 00 Brno, Czech Republic

Hereby declares that the following product:

"Factor V Leiden PCR detection kit" is classified as category D, Other Medical Agents. The kit is designed for the G1691A mutation detection in the human factor V gene (Leiden mutation) by the real-time 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 G1691G allele and for the A1691A allele of the human V factor gene.

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 documentations and with the basic requirements.

The following technical regulations, harmonized Czech technical standards or documentations and notices were used to demonstrate the compliance:
Council Directive 98/79/EC
Government Order No. 453/2004 Coll.

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



In Brno on: **March 1st, 2008**

**Assoc. Prof. RNDr. Milan Bartoš, Ph.D.
Quality Manager**

(Name and position and signature of the authorized person)

Manufacturer's stamp

