

**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:

***Mycobacterium tuberculosis* PCR Kit**

is classified in category D, Other Medical Agents. The kit is designed for the detection of a specific multicopy insertion sequence IS6110 in the *Mycobacterium tuberculosis* DNA by using the Polymerase Chain Reaction method (PCR). This method specifically detects strains of the *Mycobacterium tuberculosis* complex (*M. tuberculosis*, *M. bovis*, *M. africanum* and *M. microti*); it also detects vaccination strains (e.g. BCG). Sensitivity of the PCR detection kit runs in single copies of the IS6110 insertion sequence in a reaction. Multiple copy of these sequences in mycobacterial genome providing very high sensitivity of laboratory diagnostics of body fluids (bronchoalveolar lavage, urine) or sputa. The sensitivity is 16 times higher in comparison to the single gene detection. The kit is designed for *in vitro* diagnostics and provides qualitative detection.

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: April 7, 2008


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

(Name and position and signature of the authorized person)

Manufacturer's stamp

