

**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:

***Mycoplasma species* PCR Kit**

is classified in category D, Other Medical Agents. This kit is designed for the detection of the genomic DNA in *Mycoplasma species* by the Polymerase Chain Reaction method (PCR). This detection is focused on a multi-copy sequence of the gene encoding bacterial 16S RNA, specific for *Mycoplasma species*. Sensitivity of the PCR detection kit runs in single copies of the *Mycoplasma* genomic DNA in a PCR reaction. It provides for a sensitive, universal detection of all clinically significant human mycoplasmas and ureaplasmas, including *M. pneumoniae*, *M. hominis*, *M. genitalium*, *U. urealítica* and *M. fermentans*.

The detection kit takes an advantage of the "hot start" technology, minimizing non-specific reactions and assuring maximum sensitivity. The reaction mix includes an internal standard controlling the possible inhibition of the PCR reaction and the uracil-DNA-glycosylase (UDG) controlling possible contamination of the PCR reaction by amplification products. This kit is designed for 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: December 1st, 2007


**Assoc. Prof. RNDr. Milan Bartoš, Ph.D.,
Quality Manager**
(Name and position and signature of the authorized person)

Manufacturer's stamp

