

**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:

***Epstein-Barr Virus (EBV) PCR Kit***

is classified in category D, Other Medical Agents. EBV infection demonstration is based on the detection of a section of the specific conservative DNA sequence of a single-copy gene for the nuclear EBNA1 antigen by the Real-Time Polymerase Chain Reaction method (qPCR). The detection 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 and the uracil-DNA-glycosylase (UDG) controlling possible contamination by amplification products.

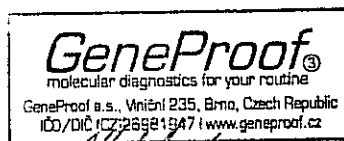
This product complies with the basic requirements of Annex No. 1 to the Government Order No. 453/2004 Coll. and under normal use it is safe for its intended purpose. The manufacturer has taken measures assuring compliance of all medical agents introduced into the market with their technical documentations 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.



A handwritten signature in black ink, appearing to read "Milan Bartoš", is written over the bottom portion of the GeneProof stamp.

In Brno on: **January 1, 2008**

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

Manufacturer's stamp