

**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:

HSV-VZV PCR Kit

is classified in category D, Other Medical Agents. This kit provides for the simultaneous detection of the Herpes simplex virus (HSV) and Varicella-Zoster virus (VZV) by the Polymerase Chain Reaction method (PCR). The VZV detection is based on the amplification of a specific conservative DNA sequence of a single-copy gene for the ORF62 (IE62 transactivator). Detection of both HSV types (HSV-1, HSV-2) is based on the PCR amplification of a specific conservative DNA sequence of a single-copy gene for glycoprotein B (gB). The procedure takes an advantage of the "hot start" technology, minimizing non-specific reactions and assuring maximum sensitivity. An internal standard is included in the reaction mix, controlling the possible inhibition of the PCR reaction. Sensitivity of the detection kit runs in single occurrences of each virus in a reaction. This provides high sensitivity for the laboratory detection in hundreds of viruses per ml in body fluid samples (liquor, serum) or blood. 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: **December 1st, 2007**


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

(Name and position and signature of the authorized person)

Manufacturer's stamp

