

**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:

Varicella-Zoster Virus (VZV) PCR Kit

is classified in category D, Other Medical Agents. This kit is designed for Varicella-Zoster virus (VZV) detection by the Real Time Polymerase Chain Reaction. The VZV detection is based on the amplification of a specific conservative DNA sequence of a single-copy ORF62 gene and on measuring the amplification product concentration in the course of the PCR process by means of a fluorophore FAM marked probe. The reaction mix includes an Internal Standard (IS) controlling the possible inhibition of the PCR reaction and the efficiency of DNA isolation process (ISEX version). Amplification of IS results in positive signal in JOE channel. The detection kit takes an advantage of the "hot start" technology, minimizing non-specific reactions and assuring maximum sensitivity and contains the uracil-DNA-glycosylase (UDG) controlling possible contamination of the PCR reaction by amplification products. Diagnostic kit sensitivity runs in single virus occurrences in a PCR reaction. This provides for a very high sensitivity of the VZV laboratory detection in body fluid (liquor, serum) and blood samples. The kit is designed for *in vitro* diagnostics and provides qualitative and quantitative detections.

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: **June 30th, 2009**

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

(Name and position and signature of the authorized person)

Manufacturer's stamp

