EC DECLARATION OF CONFORMITY

without the participation of an Notified body - diagnostic medical devices *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 and European Parliament Directive 98/79/EC dated October 27, 1998, on *in vitro* diagnostic medical agents (below only "Council Directive 98/79/EC"), requirements of which were adopted in the Czech Government Order No. 453/2004 Coll. establishing technical requirements for *in vitro* diagnostic medical agents, in the wording of later regulations (below only Government Order No. 453/2004 Coll.).

Manufacturer:

GeneProof a.s., Vídeňská 119, 619 00 Brno, Czech Republic

Hereby declares that the following product:

GeneProof BK/JC Virus (BK/JC) PCR Kit

is classified in category D, Other Medical Agents. The PCR kit is designed for BK and JC virus detection and differentiation by the real-time Polymerase Chain Reaction method (multiplex PCR). The BK/JC detection and differentiation are based on the principle of amplifying the specific conservative DNA sequence overlapping the boundary between the gene for the VP1 and VP2 proteins and measuring the concentration increase in the amplification product during the PCR process by means of a fluorescence-marked probes. BK virus presence is indicated by FAM fluorophore fluorescence increase and the JC virus presence is indicated by Cy5 fluorophore fluorescence increase. An Internal Standard (IS) is included in the reaction mix controlling the possible inhibition of the PCR reaction (ISIN version) or also the quality of DNA extraction (ISEX version). IS positive amplification is detected in the HEX fluorophore fluorescence channel. The detection kit takes an advantage of the "hot start" technology minimizing non-specific reactions and assuring maximum sensitivity. It contains uracil-DNA glycosylase (UDG) eliminating possible contamination of the PCR reaction by amplification products. Diagnostic kit sensitivity runs in single BK/JC genome copies per PCR reaction. This provides for very high sensitivity of the BK/JC virus laboratory detection in clinical material (EDTA whole blood, urine, cerebrospinal fluid). The kit is designed for *in vitro* diagnostics and provides qualitative and quantitative 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 documentation and with the basic requirements.

The following technical regulations, harmonized Czech technical standards or documentation and notice 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.

Brno on **March 12, 2014**

RNDr. Radek HORVÁTH Ph.D.
Quality Assurance/Quality Control department
Head of department
(Name, position and signature of the authorized person)

Manufacturer's stamp

GeneProof
Molecular diagnostics for your routine
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