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 devices (below only "Directive"), requirements of which were adopted in the Czech Government Order No. 453/2004 Coll. establishing technical requirements for *in vitro* diagnostic medical devices, 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 / www.geneproof.com

hereby declares that following product

GeneProof BK Virus (BKV) PCR Kit

is classified in category D, other medical devices. The PCR kit is designed for BK virus detection by the real-time Polymerase Chain Reaction method (PCR). The BK virus detection is 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 labeled probes. BK virus presence is indicated by FAM fluorophore fluorescence growth. An Internal Standard (IS) is included in the reaction mix controlling the possible inhibition of the PCR reaction (ISIN version) and possibly 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. Ready to Use MasterMix contains uracil-DNA-glycosylase (UDG) eliminating possible contamination of the PCR reaction by amplification products. The kit performs very sensitive BKV 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 devices introduced into the market with their technical documentation and with the basic requirements.

The following act and directive were used to demonstrate the compliance:

- Europe parliament and council directive 98/79/ES
- Government requlation No. 453/2004 Coll.

Procedure described in Annex No. 3 Government Order No. 453/2004 Coll. was used to evaluate the basic characteristics of the product by the designated method.

Brno on February 11, 2015

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

Manufacturer´s stamp:

GeneProof®
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