# 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 Regulation No. 453/2004 Coll. establishing technical requirements for *in vitro* diagnostic medical devices, in the wording of later regulations (below only Government Regulation No. 453/2004 Coll.).

MANUFACTURER

**GeneProof a.s., Vídeňská 119, 619 00 Brno, Czech republic / www.geneproof.com**

hereby declares that following product

## GeneProof Adenovirus PCR Kit

**is classified in category D, Medical Agents. This kit is designed for Adenovirus detection by the real-time Polymerase Chain Reaction method (PCR). The Adenovirus detection is based on the amplification of a highly conservative DNA sequence (E2B gene) and on measuring the amplification product concentration in the course of the PCR process by means of fluorescence labeled probes. Adenovirus presence is indicated by the 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 DNA extraction quality (ISEX version). IS positive amplification is detected in the fluorescence channel for the HEX fluorophore. 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 provides for detection of all Adenovirus A-G basic groups and of all sequentially accessible Adenovirus serotypes in clinical material (whole blood in EDTA, plasma, urine, aspirate, stool, nasopharyngeal, oropharyngeal swab). 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 documentation and with the basic requirements.

The following directive, regulation and decision were used to demonstrate the compliance:

- Europe Parliament and Council Directive 98/79/ES
- Government Regulation 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 March 17, 2015**

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

Manufacturer´s stamp:

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