

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. 56/2015 Coll. establishing technical requirements for *in vitro* diagnostic medical devices, in the wording of later regulations (below only Government Regulation No. 56/2015 Coll.).

MANUFACTURER

GeneProof a.s., Videnska 119, 619 00 Brno, Czech Republic / www.geneproof.com

hereby declares that following product

GeneProof Aspergillus PCR Kit

is classified in category other medical devices. The PCR kit is designed for the detection of the clinically significant representatives of the *Aspergillus* species (*A. fumigatus*, *A. flavus*, *A. niger*, *A. terreus*) by the real-time Polymerase Chain Reaction (PCR) method. The *Aspergillus* detection is based on the amplification of a specific sequence of ribosomal DNA and measuring the amplification product concentration growth using PCR process and fluorophore labelled probes. *Aspergillus* spp. presence is indicated by FAM fluorophore fluorescence growth and the presence of *Aspergillus terreus* is indicated by Cy5 fluorophore fluorescence growth. An Internal Standard (IS) is either included in the reaction mix, controlling the possible inhibition of the PCR (ISIN version) or excluded, controlling also the DNA extraction process quality (ISEX version). IS positive amplification is detected in the HEX fluorophore fluorescence channel. The detection kit utilizes 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 is designed for *in vitro* diagnostics and provides qualitative detection.

This product complies with the basic requirements of Annex No. 1 to the Government Regulation No. 56/2015 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. 56/2015 Coll.

Procedure described in Annex No. 3 of the Government Regulation No. 56/2015 Coll. was used to evaluate the basic characteristics of the product by the designated method.

Brno December 9, 2016


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

Manufacturer's stamp:

