EC DECLARATION OF CONFORMITY

without the participation of an Notified body - *in vitro* diagnostic medical devices

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 and according to the Council and European Parliament Directive 98/79/EC dated October 27, 1998, on *in vitro* diagnostic medical devices (herafter referred to as the "Europe Parliament and Council Directive 98/79/EC"), 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 (herafter referred to as the Government Regulation No. 56/2015 Coll.).

MANUFACTURER

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

hereby declares that following product

GeneProof Mycoplasma genitalium/hominis PCR Kit

is classified as other medical devices. The PCR kit is designed for *Mycoplasma genitalium* and *Mycoplasma hominis* pathogen detection by the real-time Polymerase Chain Reaction method (PCR). *M. genitalium* and *M. hominis* detection is based on the principle of amplifying the multicopy sequence of a gene encoding the 16S RNA (*M. genitalium*) and the housekeeping gene *gap* for glyceraldehyde-3-phosphate dehydrogenase (*M. hominis*) and measuring the amplification product concentration growth using the PCR and fluorophore labelled probes. *M. genitalium* presence is indicated by the FAM fluorophore fluorescence growth. *M. hominis* differentiation is indicated by the growth in the Cy5 channel. An Internal Standard (IS) is included in the reaction mix, controlling the possible inhibition of the PCR reaction (ISIN version) and the DNA isolation quality (ISEX version). IS positive amplification is detected in the fluorescence channel for the HEX fluorophore. 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 Order 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 Requlation No. 56/2015 Coll.

Procedure described in Annex No. 3 was used to evaluate the basic characteristics of the product by the designated method.

Brno November 21, 2016

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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