EC DECLARATION OF CONFORMITY

with the participation of an Notified body No. 1023 INSTITUT PRO TESTOVÁNÍ A CERTIFIKACI, a. s. třída Tomáše Bati 299, Louky 763 02 Zlín - 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 Chlamydia trachomatis PCR Kit

is classified in category B, Medical devices. The PCR kit is designed for *Chlamydia trachomatis* detection by the real-time. Polymerase Chain Reaction (PCR) method. The *C. trachomatis* detection is based on the amplification of both the cryptic plasmid multicopy sequence and the 16S RNA gene specific for *C. trachomatis* and on measuring the amplification product concentration in the course of the PCR process by means of fluorescence labeled probes. Detection of multicopy sequence of the cryptic plasmid enables very high sensitivity of chlamydia detection (including the Swedish variant) and the chromosomal gene detection at the same time enables high specificity and makes detection of plasmidless strains possible. *C. trachomatis* 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 DNA extraction process quality (ISEX version). IS positive amplification is detected in the HEX fluorophore fluorescence channel. The detection kit takes 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 *C. trachomatis* detection in clinical material (vaginal, pharyngeal, rectal swab, sperm, urine). 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. 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 act and directive were used to demonstrate the compliance:

- Europe Parliament and Council Directive 98/79/ES
- Goverment Requlation No. 453/2004 Coll.

Procedure described in Annex No. 4 Government Regulation No. 453/2004 Coll. was used to evaluate the basic characteristics of the product by the designated method and conformity is confirmed by certificate No. 14 0006 QS/NB with validity till January 19, 2019.

Brno January 29, 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
Molecular diagnostics for your routine
GeneProof a.s. / Vídeňská 119, CZ-619 00 Brno
IČ/DIČ: CZ/26981947 / www.geneproof.com

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