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

hereby declares that following product

GeneProof Human papillomavirus (HPV) PCR Kit

is classified in category other medical devices. The PCR kit is designed for the detection of high-risk types of Human Papillomavirus (HPV) by the real-time Polymerase Chain Reaction (PCR) method. The HPV detection is based on the amplification of a specific conservative DNA sequence in the area of genes *E2/E4* and measuring the amplification product concentration using PCR process and fluorophore labelled probes. HPV presence is indicated by the FAM and Cy5 fluorophore fluorescence growth. For the DNA isolation quality control and possible PCR inhibition control there are primers and probe for GAPDH gene amplification present in the reaction mix. Amplification of GAPDH gene is indicated 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 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 act and directive 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 February 12, 2016
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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