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

MANUFACTURER

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

hereby declares that following product

GeneProof Bordetella pertussis/parapertussis PCR Kit

is classified in category D, other medical devices. The PCR kit is designed for the detection and differentiation of *Bordetella pertussis* and *Bordetella parapertussis* by the Polymerase Chain Reaction (PCR) method. Bordetella detection and differentiation is based on the amplification of the multicopy insertion sequence IS1002 (specific for both bordetella species) and the multicopy insertion sequence IS1001 (specific only for *B. parapertussis*) and on measuring the growth in the amplification product concentration in the course of the PCR by means of fluorescence marked probes. One of the few kits in the market that do not provide false positive results for *Bordetella holmessii*. *B. pertussis* presence is indicated by the FAM fluorophore fluorescence growth and at the same time by the absence of fluorescence in the Cy5 channel. *B. parapertussis* presence is indicated by the fluorescence growth in FAM and Cy5 channels. An Internal Standard (IS) is included in the reaction mix, controlling the possible inhibition of the PCR reaction (ISIN version) or also the DNA extraction process 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 performs very sensitive bordetella detection in clinical material (sputum, nasal aspirate, nasopharyngeal aspirate).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. 453/2004 Coll. and under normal use it is safe for its intended purpose. The manufacturer has taken measures assuring compliance of all medical devices 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. 453/2004 Coll.

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

Brno on December 16, 2014

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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