

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 and according to the Council and European Parliament Directive 98/79/EC dated October 27, 1998, on *in vitro* diagnostic medical devices (hereafter referred to as the Europe Parliament and Council Directive 98/79/ES "), 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 (hereafter 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 *Bordetella pertussis/parapertussis* PCR Kit

is classified as other medical devices. The PCR kit is designed for *Bordetella pertussis* and *Bordetella parapertussis* detection and differentiation by the real-time Polymerase Chain Reaction (PCR) method. The *B. pertussis* and *B. parapertussis* detection and differentiation consists in amplification of the multi-copy insertion sequences IS1002 (specific for both *Bordetella pertussis/parapertussis*) and IS1001 (specific only for *B. parapertussis*) and in measurement of fluorescence increase. GeneProof *Bordetella pertussis/parapertussis* PCR Kit is one of the few kits in the market that does not provide false positive results for *Bordetella holmesii*. The *B. pertussis* presence is indicated by the FAM fluorophore fluorescence growth only. The *B. parapertussis* presence is indicated by the fluorescence growth in both FAM and Cy5 channels. 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 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 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 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, October 5, 2017

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



Manufacturer's stamp:

