

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 *Borrelia burgdorferi* PCR Kit

is classified in category D, other medical devices. The PCR kit is designed for detection of clinically important species from the *Borrelia burgdorferi sensu lato* group (*B. burgdorferi sensu stricto*, *B. afzelii*, *B. garinii*, *B. valaisiana*, *B. lusitaniae*, *B. andersonii*, *B. bissettii*, *B. japonica*, *B. tanukii*, *B. turdi*, *B. sinica*) by the real-time Polymerase Chain Reaction (PCR) method. The *B. burgdorferi* detection is based on the amplification of gene sequence encoding 16S RNA specific for the *B. burgdorferi sensu lato* group and on measuring the amplification product concentration in the course of the PCR process by means of fluorescence labelled probes. *B. burgdorferi* 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) or 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 *B. burgdorferi* detection in clinical material (EDTA whole blood, cerebrospinal fluid, urine, tick). 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 regulation No. 453/2004 Coll.

Procedure described in Annex No. 3 Government Order No. 453/2004 Coll. was used to evaluate the basic characteristics of the product by the designated method.

Brno on January 29, 2014

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



Manufacturer's stamp:

