EC DECLARATION OF CONFORMITY

without the participation of a Notified body - diagnostic medical devices *in vitro*

Pursuant to Section 13(2) of Act No 22/1997 Coll., on the Technical Requirements for Products, and on a change and addition to certain laws, as amended, and pursuant to Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices, the requirements of which have been adopted by Government Regulation 56/2015 Coll., on Technical Requirements for in vitro Diagnostic Medical Devices, as amended

MANUFACTURER

GeneProof a.s., Vídeňská 101/119, Dolní Heršpice, 619 00 Brno, Czech Republic
www.geneproof.com

hereby declares that following product

GeneProof Borrelia PCR Kit

Medical device type:	***in vitro* diagnostic medical device**
Classification:	**other diagnostic medical devices**
Intended purpose of the device:	**Kit is an *in vitro* nucleic acid amplification test intended for qualitative detection of clinically important *Borrelia* species from the *Borrelia burgdorferi sensu lato* group causing Lyme disease and for detection of *Borrelia miyamotoi* causing tick-borne relapsing fever, by real-time polymerase chain reaction (PCR) method. The clinical specimens used for the detection are cerebrospinal fluid (CSF), plasma, serum, tick, urine and whole blood. The kit can be used in combination with a manual or automated extraction system. The kit is intended for diagnostics and aid to diagnosis and it is designed for professional use in laboratories with trained staff. The diagnostic kit is designed to test specifically individuals with the signs and symptoms of Lyme disease, with the likelihood that the patient has been exposed to infected ticks. The target population is the EU population.**
Variants:	**BOR/GP/025, BOR/GP/100**

complies with the basic requirements of Annex No. 1 of the Directive 98/79/EC of the European Parliament and of the Council and the Czech Government Regulation No. 56/2015 Coll. and under normal use it is safe and effective 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 essential requirements.

Following currently valid version of the standards were applied to meet essential requirements:

ČSN EN ISO 13485 ed.2:2016	Medical device – QMS – Requirements for regulatory purposes
ČSN EN ISO 14971:2020	Medical device – QMS – Application of risk management to medical devices
ČSN EN ISO 18113-1:2012	In vitro diagnostic medical devices -- Information supplied by the manufacturer (labelling) -- Part 1 Terms, definitions and general requirements
ČSN EN ISO 18113-2:2012	In vitro diagnostic medical devices -- Information supplied by the manufacturer (labelling) -- Part 2 In vitro diagnostic reagents for professional use
ČSN EN ISO 15223-1:2017	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied, Part1: General requirements
ČSN EN ISO 23640:2016	In vitro diagnostic medical devices – Evaluation of stability of in vitro diagnostic reagents

Procedure described in Annex No. 3 of the Directive 98/79/EC of the European Parliament and of the Council and the Czech Government Regulation No. 56/2015 Coll. were used to evaluate the basic characteristics of the product by the designated method.

Brno, May 19, 2022

Kamil ŠPLÍCHAL
Quality Assurance/ Regulatory Affairs
Chief Quality and Regulatory Affairs Officer
(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