EC DECLARATION OF CONFORMITY

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

According to the 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 Directive 98/79/EC of the European Parliament and of the Council dated October 27, 1998, on *in vitro* diagnostic medical devices, 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 and in accordance with the harmonised standard ČSN EN ISO 13485 ed. 2 :2016: Medical devices – Quality management systems – Requirements for regulatory purposes

MANUFACTURER

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

hereby declares that following product

GeneProof Parvovirus B19 PCR Kit

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 basic requirements.

Medical device type:	***in vitro* diagnostic medical device**
Classification:	**other diagnostic medical devices**
Intended purpose of the device:	**for qualitative and quantitative diagnostics, aid to diagnostics or monitoring of Parvovirus B19 from body fluids by the real-time Polymerase Chain Reaction (PCR) method. The intended user are professional personnel of clinical laboratories**
Variants:	**B19/ISEX/025** **B19/ISEX/050** **B19/ISEX/100**

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, April 25, 2019

Mgr. Kamil ŠPLÍCHAL
Quality Assurance/Quality Control department
Chief Quality and Regulatory Affairs Officer
(Name, position and signature of authorized person)

Manufacturer´s stamp:

GeneProof ®
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