EC DECLARATION OF CONFORMITY

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

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 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

MANUFACTURER

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

hereby declares that following product

GeneProof Adenovirus 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 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.

Medical device type:	***in vitro* diagnostic medical device**
Classification:	**other diagnostic medical devices**
Intended purpose of the device:	**for Adenovirus detection by the real-time Polymerase Chain Reaction method (PCR)**
Variants:	**ADV/ISIN/025**
	ADV/ISIN/050
	ADV/ISIN/100
	ADV/ISEX/025
	ADV/ISEX/050
	ADV/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. was used to evaluate the basic characteristics of the product by the designated method.

Brno, December 4, 2018

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
Molecular diagnostics for your routine
GeneProof a.s. / Vídeňská 119, CZ-619 00 Brno

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