EC DECLARATION OF CONFORMITY

with the participation of Notified body No. 1023 INSTITUT PRO TESTOVÁNÍ A CERTIFIKACI, a. s. třída Tomáše Bati 299, Louky 763 02 Zlín - 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 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 according to 2009/886/EC Commission Decision dated November 27, 2009 amending Decision 2002/364/EC on common technical specification 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 HIV type 1 (HIV-1) PCR Kit

Medical device type:	***in vitro* diagnostic medical device**
Classification:	**List A, Annex II**
Intended purpose of the device:	**the kit is intended for qualitative and quantitative diagnostics, aid to diagnostics or monitoring of Human Immunodeficiency Virus type 1 from plasma by the real-time Polymerase Chain Reaction (PCR) method. The intended users are professional personnel of clinical laboratories.**
Variants:	**HIV1/ISEX/025, HIV1/ISEX/050, HIV1/ISEX/100**

complies with the essential 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 agents 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 14971:2012	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. 4 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 and conformity is confirmed by Full Quality Assurance System certificate No. 14 0005 QS/NB with validity till January 17, 2024 and Design Examination certificate No. 15 0488 CN/NB with validity till January 17, 2024.

Brno, June 27, 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
Molecular diagnostics for your routine
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IČ/DIČ: CZ/26981947 / www.geneproof.com

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