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

MANUFACTURER

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

hereby declares that following product

GeneProof Herpes Simplex Virus (HSV-1/2) PCR Kit

Medical device type: ***in vitro* diagnostic medical device**
Classification: **other diagnostic medical devices**
Intended purpose of the device: **The kit is an *in vitro* nucleic acid amplification test intended for measurement and detection of Herpes simplex viruses (HSV-1 and HSV-2) from clinical specimens: CSF, plasma, serum, urine, swab and whole blood. The kit can be used in combination with a manual or automated extraction system. The kit is designed for human *in vitro* diagnostics and provides both qualitative and quantitative detection. The kit is intended for diagnostics, aid to diagnosis or monitoring test and it is designed for professional use in laboratories with trained personnel. The intended testing population are immunocompromised patients, symptomatic sexually active individuals and patients with neuroinfections, infections of eye and skin and exanthematous diseases. The target population is the EU population.**

Variants:

Variant name	Package	REF
HSV 25 rxn	25 reactions	HSV/ISEX/025
HSV 100 rxn	100 reactions	HSV/ISEX/100
HSV 100 rxn (co-branding menu)	100 reactions	A58128

complies with the basic requirements of Annex No. 1 of the Directive 98/79/EC of the European Parliament and of the Council 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 was used to evaluate the basic characteristics of the product by the designated method.

The Declaration of Conformity issued on May 25, 2022 is kept unchanged, the update consists only in the addition of a new product variant A58128.

Brno, April 14, 2023

Kamil ŠPLÍCHAL
QA/RA Director
(Name, position and signature of authorized person)

Manufacturer´s stamp:

GeneProof®
Molecular diagnostics for your routine
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