EU DECLARATION OF CONFORMITY

Pursuant to REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on *in-vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU

MANUFACTURER

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

hereby declares that the following product

GeneProof Epstein-Barr Virus (EBV) PCR Kit

Notified Body name: **Notified Body Address:** **Notified Body Identification number:**	**BSI GROUP THE NETHERLANDS B.V** **Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands** **2797**
Single Registration Number:	**CZ-MF-000002370**
Medical device type:	***in vitro* diagnostic medical device**
Classification:	**Risk Class C, Rule 3b**
Basic UDI-DI:	**859569630001Q3**
Intended purpose and use of the device:	**The intended purpose of the device is related to the medical context and clinical conditions under which the device may be used. EBV is implicated in a number of diseases, including infectious mononucleosis, Burkitt's lymphoma, Hodgkin's lymphoma, stomach cancer, nasopharyngeal carcinoma, multiple sclerosis and lymphomatoid granulomatosis. Direct evidence of EBV DNA (PCR) is used primarily in the diagnosis of lymphoproliferative diseases in immunodeficient patients, chronic active EBV infections, neurological complications associated with EB viral infection, and in monitoring response to treatment.** **The kit is an *in vitro* nucleic acid amplification test intended for quantification and detection of Epstein-Barr Virus (EBV; Human herpesvirus 4) in the following clinical specimens: CSF, plasma, whole blood and BAL.** **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 for monitoring and it is designed for professional use in laboratories with trained staff.**
Testing population; specific information:	**The intended testing population are immunocompromised patients, patients with chronic active EBV infections and patients with neurological complications associated with EB viral infection. The target population is the EU population.**
Variants:	**EBV/GP/025** **EBV/GP/100**

complies with the general safety and performance requirements of Annex I of Regulation (EU) 2017/746 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 to the market with their technical documentation and with the general safety and performance requirements.

Brno, April 3, 2023

Kamil ŠPLÍCHAL
QA/RA Director
On behalf of GeneProof a.s.
(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: CZ26981941 www.geneproof.com

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The following legal regulations and standards (currently valid versions) were applied to meet general safety and performance requirements:

Commission Regulation (EU) 2015/830	Regulation of 28 May 2015 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)
Regulation (EC) No 1272/2008	Regulation of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006
ČSN EN ISO 13485 ed.2:2016	Medical devices – QMS – Requirements for regulatory purposes
EN ISO 14971:2019	Medical devices – QMS – Application of risk management to medical devices
EN ISO 18113-1:2011	In vitro diagnostic medical devices -- Information supplied by the manufacturer (labelling) -- Part 1 Terms, definitions and general requirements
EN ISO 18113-2:2011	In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) – Part 2 In vitro diagnostic reagents for professional use
EN ISO 15223-1:2021	Medical devices – Symbols to be used with information to be supplied by the manufacturer, Part1: General requirements
EN ISO 23640:2015	In vitro diagnostic medical devices – Evaluation of stability of in vitro diagnostic reagents
ISO 20916:2019	In-vitro diagnostic medical devices – Clinical performance studies using specimens from human subjects – Good study practice

Conformity assessment route as specified in Regulation (EU) 2017/746 of the European Parliament and of the Council, Chapters I and III of Annex IX, in combination with an assessment of the technical documentation of a representative device per generic device group, Chapter II, Section 4 of that Annex has been applied, and the conformity is confirmed by EU Quality Management System Certificate No. IVDR 733600, valid until January 10, 2028.
EU Declaration of Conformity is issued under the sole responsibility of the manufacturer.

Brno, April 3, 2023

Kamil ŠPLÍCHAL
QA/RA Director
On behalf of GeneProof a.s.
(Name, position and signature of authorized person)

Manufacturer´s stamp:

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