

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 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.

MANUFACTURER

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

hereby declares that following product

GeneProof Cytomegalovirus (CMV) PCR Kit

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

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| 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.

Brno, July 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:

