EC DECLARATION OF CONFORMITY

with the participation of an 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 in accordance with the harmonised standard ČSN EN ISO 13485 ed. 2:2016: Medical devices – Quality management systems – Requirements for regulatory purposes

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

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 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 basic requirements.

Medical device type: in vitro diagnostic medical device for professional use
Classification: List B, Annex II
Intended purpose of the device: for qualitative and quantitative diagnostics, aid to diagnostics and monitoring of human Cytomegalovirus (CMV) from body fluids by the real-time Polymerase Chain Reaction (PCR) method. The intended users is professional personnel of clinical laboratories.

Variants:
CMV/ISIN/025
CMV/ISIN/050
CMV/ISIN/100
CMV/ISEX/025
CMV/ISEX/050
CMV/ISEX/100

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, March 18, 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:

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