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


MANUFACTURER

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

hereby declares that following product

GeneProof Hepatitis C Virus (HCV) 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 devices introduced into the market with their technical documentation and with the basic requirements.

Medical device type: in vitro diagnostic medical device
Classification: List A, Annex II
Intended purpose of the device: for the Hepatitis C virus (HCV) RNA qualitative and quantitative detection from body fluids by the real-time Polymerase Chain Reaction (PCR) method. The intended users are professional personnel of clinical laboratories

Variants:
HCV/PLUS/025
HCV/PLUS/050
HCV/PLUS/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 and Design Examination certificate No. 16 0576 CN/NB with validity till December 15, 2021.

Brno, April 25, 2019

Mgr. Kamil ŠPLÍCHAL
Quality Assurance/Qaulity Control department
Chief Quality and Regulatory Affairs Officer
(Name, position and signature of authorized person)

Manufacturer's stamp:

GeneProof
Molecular diagnostics for your routine