EC DECLARATION OF CONFORMITY
without the participation of a Notified body - 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
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hereby declares that following product

GeneProof Human Papillomavirus (HPV) Screening PCR Kit

Medical device type: in vitro diagnostic medical device
Classification: other diagnostic medical devices
Intended purpose of the device: Kit is intended for qualitative diagnostics, aid to diagnostics and screening of Human Papillomavirus (HPV) by the real-time Polymerase Chain Reaction (PCR) method. The intended users are professional personnel of clinical laboratories.
Variants: HPVS/GP/025, HPVS/GP/050, HPVS/GP/100

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. 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 14971:2012 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

Procedure described in Annex No. 3 of the Directive 98/79/EC of the European Parliament and of the Council and the Czech Government Regulation No. 56/2015 Coll. were used to evaluate the basic characteristics of the product by the designated method.

Brno, January 31, 2020
RNDr. Radek Horváth, Ph.D.
Chief Executive Officer
(Name, position and signature of authorized person)

Manufacturer’s stamp:
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