

# 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**  
**www.geneproof.com**

hereby declares that following product

## GeneProof Universal Internal Control

<b>Medical device type:</b>	<b><i>in vitro</i> diagnostic medical device</b>
<b>Classification:</b>	<b>other diagnostic medical devices</b>
<b>Intended purpose of the device:</b>	<b>Universal internal control is intended for use as a complementary product for all GeneProof microbiological PCR kits. The universal internal control presents internal control used as a control for the whole diagnostic process, i.e. DNA/RNA extraction efficiency, reverse-transcription step efficiency (transcription of RNA into cDNA) and PCR amplification efficiency (PCR inhibition). The product is intended for use in combination with manual, semiautomated and automated extraction from various clinical specimens: whole blood, CSF, plasma, serum, urine, BAL. The intended users are professional personnel of clinical laboratories.</b>
<b>Variants:</b>	<b>UNIC/GP/010, UNIC/GP/050</b>

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 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
ČSN EN ISO 23640:2016	In vitro diagnostic medical devices – Evaluation of stability of in vitro diagnostic reagents

**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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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: