

# EC DECLARATION OF CONFORMITY

without the participation of an Notified body - 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 (below only the "Act") and according to the Council and European Parliament Directive 98/79/EC dated October 27, 1998, on *in vitro* diagnostic medical devices (below only "Directive"), requirements of which were adopted in the Czech Government Order No. 453/2004 Coll. establishing technical requirements for *in vitro* diagnostic medical devices, in the wording of later regulations (below only Government Order No. 453/2004 Coll.).

MANUFACTURER

**GeneProof a.s., Vídeňská 119, 619 00 Brno, Czech Republic / [www.geneproof.com](http://www.geneproof.com)**

hereby declares that following product

## GeneProof PathogenFree RNA Isolation Kit

is classified in category D, other medical devices. The kit for column RNA isolation. It is designed for use in diagnostic and research laboratories dealing with routine PCR diagnostics of RNA viruses. Owing to a special column design the kit provides user simple, efficient and very quick RNA isolation from clinical material. The kit is designed mostly for RNA isolation from serum and plasma.

This product complies with the basic requirements of Annex No. 1 to the Government Order No. 453/2004 Coll. and under normal use it is safe 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.

The following act and directive were used to demonstrate the compliance:

- Europe parliament and council directive 98/79/ES
- Government regulation No. 453/2004 Coll.

Procedure described in Annex No. 3 Government Order No. 453/2004 Coll. was used to evaluate the basic characteristics of the product by the designated method.

Brno on February 12, 2015

RNDr. Radek HORVÁTH, Ph.D.  
Quality Assurance/Quality Control department  
Head of department  
(Name, position and signature of authorized person)



Manufacturer's stamp:

