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

hereby declares that following product

GeneProof PathogenFree DNA Isolation Kit

is classified in category D, other medical devices. The kit for the column DNA isolation. It is designed to be used in diagnostic and research laboratories dealing with routine PCR diagnostics of pathogenic microorganisms (bacteria, candidas and fungi, viruses and protozoa) or in human genetic diagnostics. Owing to a special column design the kit provides user simple, efficient and very quick DNA isolation from clinical materials as whole peripheral blood, sputum and synthetic sputum, urine, smear and swab, bronchoalveolar lavage (BAL), cerebrospinal fluid (CSF, liquor) and synthetic CSF, saliva and biopsy.

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 requlation 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 March 31, 2015

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

Manufacturer´s stamp:

GeneProof
Molecular diagnostics for your routine
GeneProof a.s. / Vídeňská 119, CZ-619 00 Brno
IČ/DIČ: CZ26981947 / www.geneproof.com

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