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 Regulation No. 56/2015 Coll. establishing technical requirements for *in vitro* diagnostic medical devices, in the wording of later regulations (below only Government Regulation No. 56/2015 Coll.).

MANUFACTURER

GeneProof a.s., Vídeňská 119, 619 00 Brno, Czech republic / www.geneproof.com

hereby declares that following product

croBEE 201A Nucleic Acid Extraction Kit

is classified in category other medical devices. The kit is designed for DNA/RNA isolation using the croBEE NA16 Nucleic Acid Extraction System.

It provides simultaneous nucleic acids isolation from various biological material types due to the universal reagent cartridge. All the necessary reagents and consumables are included in the package. All components, plastics and disposable reagent cartridges contained in the croBEE 201A Nucleic Acid Extraction Kit are DNase/RNase-Free.

This product complies with the basic requirements of Annex No. 1 to the Government Order No. 56/2015 Coll. and under normal use it is safe for its intended purpose. The manufacturer has taken measures assuring compliance of all medical agents introduced into the market with their technical documentation and with the basic requirements.

The following directive, regulation and decision were used to demonstrate the compliance:

- Europe Parliament and Council Directive 98/79/ES
- Czech republic Government Requlation No. 56/2015 Coll.

Procedure described in Annex No. 3 of Czech republic Government Regulation No. 56/2015 was used to evaluate the basic characteristics of the product.

Brno on April 1, 2016

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
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