EC DECLARATION OF CONFORMITY

without the participation of an Notified body - *in vitro* diagnostic medical devices

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 and according to the Council and European Parliament Directive 98/79/EC dated October 27, 1998, on *in vitro* diagnostic medical devices (hereinafter referred to as "Europe Parliament and Council Directive 98/79/EC"), 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 (hereinafter referred to as "Government Regulation No. 56/2015 Coll".).

MANUFACTURER

GeneProof a.s., Videnska 119, 619 00 Brno, Czech Republic / www.geneproof.com

hereby declares that following product

GeneProof Aspergillus Pretreatment Sample Set

is classified in category other medical devices. The Sample Pretreatment Set is designed for use in diagnostic laboratories dealing with routine PCR diagnostics of clinically significant representatives of the *Aspergillus* species. The sample pretreatment step allows disintegration of the fungal cell wall, which subsequently increases the efficiency of DNA extraction. The set is designed for fungal DNA extraction from many types of clinical materials (blood, plasma, serum, CSF, sputum and BAL).

This product complies with the basic requirements of Annex No. 1 to the Government Regulation 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/EC
- Government Requlation No. 56/2015 Coll.

Procedure described in Annex No. 3 of Government regulation No. 56/2015 Coll. was used to evaluate the basic characteristics of the product by the designated method.

Brno September 7, 2016

RNDr. Radek HORVATH 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. / Videňská 119, CZ-619 00 Brno
IČ/DIČ: CZ/26981947 / www.geneproof.com

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