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

croBEE NA16 Nucleic Acid Extraction System Plus

Medical device type:	***in vitro* diagnostic medical device**
Classification:	**other diagnostic medical devices**
Intended purpose of the device:	**for simultaneous nucleic acid extraction from a wide range of biological materials**
Variants:	**CBNA/16P**

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.

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

- Standard EN 61326-1:2013 Electrical equipment's for measurement, control and laboratory use – EMC requirements – Part 1: General requirements.
- Standard EN 61326-2-6:2013 Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment
- Standard EN 61000-3-2:2014 Electromagnetic compatibility (EMC) - Part 3-2: Limits - Limits for harmonic current emissions (equipment input current ≤ 16 A per phase)
- Standard EN 61000-3-3:2013 Electromagnetic compatibility (EMC) - Part 3-3: Limits - Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current ≤ 16 A per phase and not subject to conditional connection
- Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on the harmonization of the laws of the Member States relating to electromagnetic compatibility [1]
- Regulation No. 117/2016 of the Czech Republic government of 18 April 2016 relating to the products electromagnetic compatibility conformity assessment [1]

[1] Equipment which is in conformity with harmonized standards or parts thereof the references of which have been published in the Official Journal of the European Union shall be presumed to be in conformity with the essential requirements set out in legislation (Annex I, 2014/30/EU) covered by those standards or parts thereof.

Brno, March 17, 2020

Kamil ŠPLÍCHAL
Quality Assurance/Quality Control department
Chief Quality and Regulatory Affairs Officer
(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

EC DECLARATION OF CONFORMITY

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

The following directive, act and standard were used to demonstrate the electric safety compliance:

- Standard 61010-1:2010 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements.
- Directive 2014/35/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits [2]
- Regulation No. 118/2016 of the Czech Republic government of 18 April 2016 relating to the conformity assessment of the electrical equipment's designed for use within certain voltage limits.[2]

[2] Electrical equipment which is in conformity with harmonised standards or parts thereof the references of which have been published in the Official Journal of the European Union shall be presumed to be in conformity with the safety objectives referred to in legislation Article 3 and set out in Annex I Directive 2014/35/EU covered by those standards or parts thereof.

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, March 17, 2020

Kamil ŠPLÍCHAL
Quality Assurance/Quality Control department
Chief Quality and Regulatory Affairs Officer
(Name, position and signature of authorized person)

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