

EC DECLARATION OF CONFORMITY

without the participation of a 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 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
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hereby declares that following product

croBEE Real-Time PCR System

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 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.

Medical device type:	<i>in vitro</i> diagnostic medical device
Classification:	other diagnostic medical devices
Intended purpose of the device:	for nucleic acids amplification and detection and complex analysis of obtained data
Variants:	CBRT4/96 CBRT5/96

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. was used to evaluate the basic characteristics of the product by the designated method.

The following directive, act and standard 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.
- 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 compatibility¹.
- Regulation No. 117/2016 of the Czech Republic government of 18 April 2016 relating to the products electromagnetic compatibility conformity assessment¹.

¹Equipment 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 July 19, 2018

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

Manufacturer's stamp:



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

- Standard EN 61010-2-010:2003 Safety requirements for electrical equipment for measurement, control and laboratory use Part 2-010: Particular requirements for laboratory equipment for the heating of material
- Standard EN61010-1:2010 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 harmonization of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits².
- 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 limits².

²Electrical 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 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.

Brno July 19, 2018

Mgr. Kamil ŠPLÍCHAL
Quality Assurance/Quality Control department
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