BIOPOA

DECLARATION OF CONFORMITY

CE

Legal Manufacturer	**BioPOA Co., Ltd.** **Address:** 593-26, Dongtangiheung-ro, Hwaseong-si, Gyeonggi-do, 18469, Republic of Korea Tel: +82-31-375-8304 Fax: +82-31-375-8305 Web: www.biopoa.com
European Representative	**KTR Europe GmbH** **Address:** Mergenthalerallee 77, Eschborn, 65760, Germany
Product	In vitro polymerase chain reaction (PCR) assay for COVID-19 For Professional Use Only Rapid COVID-19 PoaCheck™
EDMA code/Term	15.04.40.90.00 Other Virology-NA reagents
Classification Under IVDD	Others of AnnexⅡ, IVDD 98/79/EC

Conformity assessment Route: Annex Ⅲ

General Applicable Directive

In Vitro Diagnostic Medical Devices DIRECTIVE 98/79/EC

Standards we are implementing

EN ISO 13485: 2016	Medical devices – Quality management systems – Requirements for regulatory purposes
GMP	Manufacturer complies with Korea Good Manufacturing Practices of Medical Devices for the Reagent for in vitro Diagnostic Medical Devices.

We hereby declare that the product mentioned above meets the provisions of the European Directive 98/79/EC for in vitro Diagnostic Medical Devices. All supporting documentations are retained at the premises of the manufacturer and manufacturer is exclusively responsible for the declaration of conformity.

Place: Hwaseong-si, Republic of Korea

Date of Issue: August 3rd, 2020

Valid From: August 3rd, 2020

Signature

SUN HEE, Cho
CEO of BioPOA Co., Ltd.