Eon Biotechnology Limited
Tel: +44 203-7610121 Email: info@eonbt.com

EC Declaration of Conformity

According to Directive 98/79/EC on in-vitro-diagnostic devices, Annex III

Product Name	**EONBT COVIDAG 2019-nCOV-RBD Rapid Antigen Detection Kit**
Name and address of the Manufacturer	Eon Biotechnology Limited 110, Hilmanton Road, Lower Earley, Reading, RG6 4HJ United Kingdom
Authorised Representative	Diadeni sro ICO 02489902 Velešinska 659 - 19900 Praha, Czech Republic Contact details : Mr Bashkim Binaku, Tel: +420733677257 eMail: diadenicz@seznam.cz
Conformity Assessment Route	Directive 98/79/EC Annex III

We herewith declare on our sole responsibility that all batches of above In-vitro-diagnostic device is conform with the Essential Requirements Annex I of the directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices. The product is suitable for the intended application (only professional users). Relevant standards and guidelines are applied.

Valid from 15 February 2021

EON BIOTECHNOLOGY LONDON UK Regd No.12589814 www.eonbt.com

Suraz Kottakki, Director
Eon Biotechnology Limited
London

Certificate of Compliance

CE

"We hereby declare that the technical file of product complied with the requirement of Medical Devices Directive (MDD) 93/42/EEC as amended, In Vitro Diagnostic Directive 98/79/EC as amended & Regulation (EU) 2017/746 on In Vitro Diagnostic Medical Devices"

Certificate No.: CE-11747

Manufacturer

Name : EON BIOTECHNOLOGY LIMITED

Address : 110 HILMANTON, LOWER EARLEY, READING, ENGLAND, RG6 4HJ

Product : MEDICAL/SCIENTIFIC DEVICES OR EQUIPMENT'S, REAGENTS.
NON-ACTIVE AND NON-IMPLANTABLE MEDICAL SCIENTIFIC DEVICES.

The Certification body has performed an audit of the above product quality system covering the design, manufacture and final inspection of the certified product. The quality system has been assessed, approved and is subject to continuous surveillance according to of Medical Devices Directive (MDD) 93/42/EEC as amended, In Vitro Diagnostic Directive 98/79/EC as amended & Regulation (EU) 2017/746 on In Vitro Diagnostic Medical Devices

This certificate is issued under the following conditions:

1. It applies only to the quality system maintained in the manufacture of above referenced models and it does not substitute the design or type-examination procedures, ifrequested
2. The certificate remains valid until the manufacturing conditions or the quality systems arechanged
3. The certificate validity is conditioned by positive results or surveillance audits. The CE mark as shown above can be used, under the responsibility of the manufacturer, after completion of an EC Declaration of conformity and compliance with all relevant EC Directives. The statement is based on a single evaluation of one sample of above mentioned product. It does not imply an assessment of the whole production..

Validity of this certificate can be verified at www.eurocertverify.com

Date of Certification	30th October2020
1st Surveillance Audit Due	29th October2021
2nd Surveillance Audit Due	29th October2022
Certificate Expiry (subject to thecompany maintaining its system to the requiredstandard)	29th October2023

Authorised Signatory

EUROCERT INSPECTION LIMITED ★ Management System Certification ★ EUROCERT INSPECTION LIMITED

International House, 10 Churchill Way, Cardiff, United Kingdom, CF10 2HE
Website:- www.eurocertverify.com, Email:- info@eurocertverify.com
Company No. 11956886

Certificate of Compliance

This is to certify that the

EON BIOTECHNOLOGY LIMITED

at

110 HILMANTON, LOWER EARLEY, READING, ENGLAND, RG6 4HJ

has been assessed and found to be conforming the requirements of the

FDA

MANUFACTURING & PRODUCTION, RESEARCH & DEVELOPMENT, SUPPORT SERVICE, STORAGE, SERVICE CENTRE, IMPORT & RE-EXPORT, MARKETING & SALES PROMOTION OF REAGENTS AND NON-ACTIVE AND NON-IMPLANTABLE MEDICAL SCIENTIFIC DEVICES.

Certificate Number: 2020103018

This certificate is issued under the following conditions:

1. It applies only to the quality system maintained in the manufacture of above referenced scope / activities.
2. The certificate remains valid until the manufacturing conditions or the quality systems are changed and is subject to continuous surveillance according to the FDA Guidelines
3. The certificate validity is conditioned by positive results or surveillance audits

Validity of this certificate can be verified at www.eurocertverify.com

Date of Certification	30th October 2020
1st Surveillance Audit Due	29th October 2021
2nd Surveillance Audit Due	29th October 2022
Certificate Expiry (subject to the company maintaining its system to the required standard)	29th October 2023

Authorised Signatory

FDA compliant

EUROCERT INSPECTION LIMITED ★ Management System Certification ★ EUROCERT INSPECTION LIMITED

Certificate of Compliance

Certificate Number: 2020103017

HIPAA Compliant

2020-2021

EUROCERT Validates that

EON BIOTECHNOLOGY LIMITED

110 HILMANTON, LOWER EARLEY, READING, ENGLAND, RG6 4HJ

PRODUCT OR SERVICE RANGES:

SATISFIES HIPAA SECURITY STANDARD
THE EON HEALTH APPLICATION COMPLIES WITH HIPAA'S STRICT TECHNICAL, PHYSICAL, AND ADMINISTRATIVE SECURITY SAFEGUARDS AND STANDARDS.

ENCRYPTS DATA END-TO-END
END-TO-END ENCRYPTION PROTECTS ALL HEALTH DATA PASSED WITHIN THE EON SYSTEM.

COMPLIES WITH PRIVACY LAWS
EON BIOTECHNOLOGY SERVES AS A HIPAA BUSINESS ASSOCIATE OF LABORATORIES THAT ADMINISTER EON COVID-19 DIAGNOSTIC TESTS

has been validated

HIPAA Compliant as of October 2020

Validity of this certificate can be verified at www.eurocertverify.com

Date of Certification	30th October 2020
1st Surveillance Audit Due	29th October 2021
2nd Surveillance Audit Due	29th October 2022
Certificate Expiry (subject to the company maintaining its system to the required standard)	29th October 2023

Authorised Signatory

HIPAA COMPLIANT

Certificate of Compliance

Certificate Number:- 2020103019

This is to certify that

EON BIOTECHNOLOGY LIMITED

at

110 HILMANTON, LOWER EARLEY, READING, ENGLAND, RG6 4HJ

Has been successfully implemented the Quality management System and found working satisfactorily as per the norms of **"Good Manufacturing Practice"** as laid down by "**World Health Organisation** "which has been in conformance to the requirements of

WHO-GMP

MANUFACTURING & PRODUCTION, RESEARCH & DEVELOPMENT, SUPPORT SERVICE, STORAGE, SERVICE CENTRE, IMPORT & RE-EXPORT, MARKETING & SALES PROMOTION OF REAGENTS AND NON-ACTIVE AND NON-IMPLANTABLE MEDICAL SCIENTIFIC DEVICES.

This certificate is issued under the following conditions:

1. It applies only to the quality system maintained in the manufacture of above referenced Models Products.
2. The certificate remains valid until the manufacturing conditions or the quality systems are changed and is subject to continuous surveillance according to the WHO-GMP Guidelines
3. The certificate validity is conditioned by positive results or surveillance audits.

Validity of this certificate can be verified at www.eurocertverify.com

Date of Certification	30th October 2020
1st Surveillance Audit Due	29th October 2021
2nd Surveillance Audit Due	29th October 2022
Certificate Expiry (subject to the company maintaining its system to the required standard)	29th October 2023

Authorised Signatory