

# CERTIFICATE OF REGISTRATION



*This is to Certify that the  
Quality Management System  
of*

## **EON BIOTECHNOLOGY LIMITED**

110 HILMANTON, LOWER EARLEY, READING ENGLAND RG6 4HJ

has been independently assessed and is compliant  
with the requirements of

### **ISO 9001:2015**

This Certificate is applicable to the following product or service ranges:

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

*:: Certificate No :: GB53440A*

Date of initial registration	05 November 2020
Date of this Certificate	05 November 2020
Surveillance audit on or before	04 November 2021
Recertification Due / Certificate expiry	04 November 2023

This Certificate is remains valid subject to satisfactory surveillance audits.



*Emmanuel*  
**Emmanuel ADEMOSU**  
Director

For verification and updated information concerning the present certificate visit to [http://staunchlyservices.com/search\\_certified\\_client.php](http://staunchlyservices.com/search_certified_client.php)  
This Certificate is the property of Staunchly Management & System Services Limited and shall be returned immediately when demanded

#### **STAUNCHLY MANAGEMENT AND SYSTEM SERVICES LIMITED**

Labrynth Business Centre, 43 Middle Hill Gate, Stockport,  
Great Manchester, England-SK1 3DG  
Web :- [www.staunchlyservices.com](http://www.staunchlyservices.com)  
E-mail :- [info@staunchlyservices.com](mailto:info@staunchlyservices.com)  
Phone :- +44 345 680 0199

Company Registered in England and Wales with Company Number 11488683



◆ CERTIFICADO ◆ CERTIFICAT ◆ CERTIFICATE ◆ ЗЕРТИФИКАТ

# CERTIFICATE OF REGISTRATION



*This is to Certify that the  
Medical Devices – Quality Management System  
of*

## **EON BIOTECHNOLOGY LIMITED**

110 HILMANTON, LOWER EARLEY, READING ENGLAND RG6 4HJ

has been independently assessed and is compliant  
with the requirements of

### **ISO 13485:2016**

This Certificate is applicable to the following product or service ranges:

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

*:: Certificate No :: GB53440H*

Date of initial registration	05 November 2020
Date of this Certificate	05 November 2020
Surveillance audit on or before	04 November 2021
Recertification Due / Certificate expiry	04 November 2023

This Certificate is remains valid subject to satisfactory surveillance audits.



*Emmanuel*  
**Emmanuel ADEMOSU**  
Director

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Phone :- +44 345 680 0199

Company Registered in England and Wales with Company Number 11488683



SMS/FM/001/REV06

# Certificate of Compliance



"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:** · 1. RTqPCR COVID 19 TEST KITS, 2. RAPID ANTIGEN COVID 19 TEST KITS - NASAL/ORAL/BLOOD BASED, 3. RAPID ANTIGEN COVID 19 TEST KITS - SALIVA BASED ,4. RAPID ANTIBODY COVID 19 TEST KITS- IgG, IgM ,5. RAPID ANTIGEN & ANTIBODY COMBO COVID 19 TEST KITS ,6. ELISA COVID 19 ANTIBODIES TEST KITS,7. ELISA COVID 19 ANTIGEN TEST KITS,8. DENGUE ELISA IGG,IGM,NS1 ,9. DENGUE IGM,IGG-NS1 COMBO DEVICE (RAPID TEST) .10. MALARIA PF/PV ANTIGEN DEVICE (RAPID TEST) ,11. MALARIA PF/PAN ANTIGEN DEVICE (RAPID TEST) ,12. TROPANIN I DEVICE (RAPID TEST)

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, if requested
2. The certificate remains valid until the manufacturing conditions or the quality systems are changed
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](http://www.eurocertverify.com)**

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

  
**Authorised Signatory**



This certificate is the property of Eurocert Inspection Limited and shall be returned immediately on request.  
International House, 10 Churchill Way, Cardiff, United Kingdom, CF10 2HE  
Website:- [www.eurocertverify.com](http://www.eurocertverify.com), Email:- [info@eurocertverify.com](mailto:info@eurocertverify.com)  
Company No. 11956886

# 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](http://www.eurocertverify.com)**

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

  
Authorised Signatory



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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

1. RTqPCR COVID 19 TEST KITS, 2. RAPID ANTIGEN COVID 19 TEST KITS - NASAL/ORAL/BLOOD BASED,3. RAPID ANTIGEN COVID 19 TEST KITS - SALIVA BASED ,4. RAPID ANTIBODY COVID 19 TEST KITS - IgG, IgM ,5. RAPID ANTIGEN & ANTIBODY COMBO COVID 19 TEST KITS ,6. ELISA COVID 19 ANTIBODIES TEST KITS,7. ELISA COVID 19 ANTIGEN TEST KITS,8. DENGUE ELISA IGG,IgM,NS1 ,9. DENGUE IGM,IgG-NS1 COMBO DEVICE (RAPID TEST) .10. MALARIA PF/PV ANTIGEN DEVICE (RAPID TEST) ,11. MALARIA PF/PAN ANTIGEN DEVICE (RAPID TEST) ,12. TROPANIN I DEVICE (RAPID TEST)

**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](http://www.eurocertverify.com)

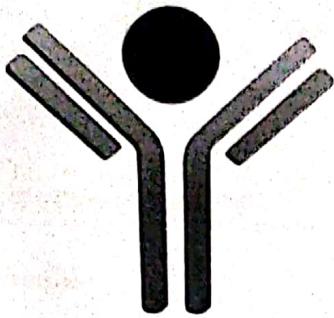
Date of Certification	30thOctober2020
1 <sup>st</sup> Surveillance Audit Due	29th October2021
2 <sup>nd</sup> Surveillance Audit Due	29th October2022
Certificate Expiry (subject to the company maintaining its system to the required standard)	29thOctober2023

  
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International House, 10 Churchill Way, Cardiff, United Kingdom, CF10 2HE  
Website:- [www.eurocertverify.com](http://www.eurocertverify.com), Email:- [info@eurocertverify.com](mailto:info@eurocertverify.com)  
Company No. 11956886

# Arista Biologicals Inc.



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ALLENTOWN, PA 18101, U.S.A.  
PHONE 484223-0309  
FAX 484223-0318  
E-MAIL [INFO@ARISTABIOLOGICALS.COM](mailto:INFO@ARISTABIOLOGICALS.COM)  
WEBSITE [WWW.ARISTABIOLOGICALS.COM](http://WWW.ARISTABIOLOGICALS.COM)

## Certificate of Analysis

**Product:** Goat anti Mouse IgG  
**Product No.:** ABGAM-0500  
**Lot No.:** 031332297  
**Quantity:** 1,000 mg  
**Concentration:** 7.82 mg/ml  
**Description:** Antibody was immunoaffinity purified from whole goat antisera  
**Preservative:** 0.02% Sodium Azide  
**Buffer:** Phosphate Buffered Saline pH 7.4  
**Storage:** 2-8° C  
**Date of Mfg:** March 13, 2020  
**Expires:** March 13, 2022

**Not for human, therapeutic, or in-vivo use.  
For research and further manufacturer use only.**

A handwritten signature in black ink that reads "Beth Szilagyi". The signature is fluid and cursive.

Beth Szilagyi, Director of Operations