Dr. Adams®

Laboratories

eDiagnosis

Certification and Specification

CERTIFICATE

武汉明德生物科技股份有限公司
2021 -07- 28
Wuhan EasyDiagnosis Biomedicine Co., Ltd

EC Certificate No. 1434-IVDD-444/2021

EC Design-examination
Directive 98/79/EC concerning
***in vitro* diagnostic medical devices**

Polish Centre for Testing and Certification certifies
that manufactured by:

Wuhan EasyDiagnosis Biomedicine Co., Ltd.
Room 3 & 4, 2nd Floor, Bldg 25, Phase 3.1,
Wuhan Optics Valley International Biopharmaceutical Enterprise Accelerator,
No. 388, Gaoxin 2nd Road, East Lake Hi-Tech Development Zone, Wuhan,
430074, Hubei, P.R. China

in vitro diagnostic medical devices
for self-testing

COVID-19(SARS-CoV-2) Antigen Test Kit

REF: W-AgH-01S, W-AgH-01, W-AgH-05S, W-AgH-05, W-AgH-07, W-AgH-07S, W-AgH-08S, W-AgH-08, W-AgH-10S, W-AgH-10, W-AgH-15S, W-AgH-15, W-AgH-20S, W-AgH-20, W-AgH-25S, W-AgH-25

in terms of design documentation, comply with requirements
of Annex III (Section 6) to Directive 98/79/EC (as amended)
implemented into Polish law,
as evidenced by the audit conducted by the PCBC
Validity of the Certificate: from 28.07.2021 to 27.05.2024

The date of issue of the Certificate: 28.07.2021

The date of the first issue of the Certificate: 13.07.2021

CE 1434

Issued under the Contract No. MD-81/2021
Application No: 157a/2021
Certificate bears the qualified signature.
Warsaw, 28/07/2021
Module A1

Anna Małgorzata Wyroba
Elektronicznie podpisany przez Anna Małgorzata Wyroba
Data: 2021.07.27 14:48:51 +02'00'

Vice-President
Mgr Anna Wyroba

TÜVRheinland®

Certificate

Quality Management System
EN ISO 13485:2016

Registration No.: SX 2055510-1

Organization: Wuhan EasyDiagnosis Biomedicine Co., Ltd.
Room 3 & 4, 2nd Floor, Bldg 25,Phase 3.1 Wuhan Optics Valley International Biopharmaceutical Enterprise Accelerator, No.388, Gaoxin 2nd RD, East Lake Hi-Tech Development Zone
Wuhan,430074 Hubei P.R. China

Scope: Design and Development, Manufacture and Distribution of In-Vitro-Diagnostic Test Kits for the Diagnosis of Cancer, Amniorrhexis, Thrombotic Diseases and Hypercoagulation, Cardiac Markers, Kidney Function Testing, Immune Status, Pregnancy Testing, Prostate Function, Diabetes Testing, Neurodegenerative Diseases, Endocrine Disorders, Infection Diseases, Disease Status, Blood Gases and Genetic Testing as well as for the Monitoring of the Disease Status including Near Patient/Point of Care, Immune Quantitative Analyzer, Full Automatic Chemiluminescence Analyzer, Chemiluminescence Immunoassay Analyzer, HbA1c Analyzer, Blood Gas Analyzer, Portable ECG, Fluorescence Immunity Analyzer, Real-time PCR System.

武汉明德生物科技股份有限公司
2021 -01- 28
Wuhan EasyDiagnosis Biomedicine Co., Ltd

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 190129510 110

Effective date: 2021-01-27

Expiry date: 2024-01-26

Issue date: 2021-01-25

DAkkS
Deutsche Akkreditierungsstelle
D-ZM-14169-01-02

Wenxiang Zhang
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜVRheinland®

Certificate

Quality Management System
EN ISO 13485:2016

Registration No.: SX 2055510-1

Organization: Wuhan EasyDiagnosis Biomedicine Co., Ltd.
Room 3 & 4, 2nd Floor, Bldg 25, Phase 3.1 Wuhan Optics Valley International Biopharmaceutical Enterprise Accelerator, No.388, Gaoxin 2nd RD, East Lake Hi-Tech Development Zone, Wuhan, 430074 Hubei, P.R. China

The scope of certification also covers the following:

No.	Facility	Scope
/01	c/o Wuhan EasyDiagnosis Biomedicine Co., Ltd. Room 3 & 4, 2nd Floor, Bldg 25, Phase 3.1 Wuhan Optics Valley International Biopharmaceutical Enterprise Accelerator, No.388, Gaoxin 2nd RD, East Lake Hi-Tech Development Zone, Wuhan, 430074 Hubei, P.R. China	Design and Development, Manufacture of In-Vitro-Diagnostic Test Kits for the Diagnosis of Cancer, Amniorrhexis, Thrombotic Diseases and Hypercoagulation, Cardiac Markers, Kidney Function Testing, Immune Status, Pregnancy Testing, Prostate Function, Diabetes Testing, Neurodegenerative Diseases, Endocrine Disorders, Infection Diseases, Disease Status, Blood Gases and Genetic Testing as well as for the Monitoring of the Disease Status including Near Patient/Point of Care
/02	c/o Wuhan EasyDiagnosis Biomedicine Co., Ltd. Room 4, 1st Floor, Bldg 25, Phase 3.1 Wuhan Optics Valley International Biopharmaceutical Enterprise Accelerator, No.388, Gaoxin 2nd Road, East Lake High-Tech Development Zone, Wuhan, 430074 Hubei, P.R. China	Design and Development, Manufacture of Immune Quantitative Analyzer, Full-automatic Chemiluminescence Analyzer, Chemiluminescence Immunoassay Analyzer, HbAlc Analyzer, Blood Gas Analyzer, Portable ECG, Fluorescence Immunity Analyzer, Real-time PCR System.

Report No.: 190129510 110

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Deutsche Akkreditierungsstelle
D-ZM-14169-01-02

Wenxiang Zhang
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜVRheinland®

Certificate

Quality Management System
EN ISO 13485:2016

Registration No.: SX 2055510-1

Organization: Wuhan EasyDiagnosis Biomedicine Co., Ltd.
Room 3 & 4, 2nd Floor, Bldg 25, Phase 3.1 Wuhan Optics Valley International Biopharmaceutical Enterprise Accelerator, No.388, Gaoxin 2nd RD, East Lake Hi-Tech Development Zone, Wuhan, 430074 Hubei, P.R. China

The scope of certification also covers the following:

/03	c/o Wuhan EasyDiagnosis Biomedicine Co., Ltd. No.A8, 2-2 Building, Optics Valley Biomedical Industry Park Phase II, No.858 Gaoxin Road, Wuhan East Lake Hi-tech Development Zone, Wuhan, 430074 Hubei, P.R. China	Design and Development, Manufacture of In-Vitro-Diagnostic Test Kits for the Diagnosis of Cancer, Amniorrhexis, Thrombotic Diseases and Hypercoagulation, Cardiac Markers, Kidney Function Testing, Immune Status, Pregnancy Testing, Prostate Function, Diabetes Testing, Neurodegenerative Diseases, Endocrine Disorders, Infection Diseases, Disease Status as well as for the Monitoring of the Disease Status including Near Patient/Point of Care. Distribution of In-Vitro-Diagnostic Test Kits for the Diagnosis of Cancer, Amniorrhexis, Thrombotic Diseases and Hypercoagulation, Cardiac Markers, Kidney Function Testing, Immune Status, Pregnancy Testing, Prostate Function, Diabetes Testing, Neurodegenerative Diseases, Endocrine Disorders, Infection Diseases, Disease Status, Blood Gases and Genetic Testing as well as for the Monitoring of the Disease Status including Near Patient/Point of Care, Immune Quantitative Analyzer, Full-automatic Chemiluminescence Analyzer, Chemiluminescence Immunoassay Analyzer, HbAlc Analyzer, Blood Gas Analyzer, Portable ECG, Fluorescence Immunity Analyzer, Real-time PCR System.

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DAkkS
Deutsche Akkreditierungsstelle
D-ZM-14169-01-02

Wenxiang Zhang
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

Business Stream Products
Certification Department

TÜVRheinland®
LGA
Precisely Right.

TÜV Rheinland LGA Products GmbH • 51105 Köln

Wuhan EasyDiagnosis Biomedicine Co., Ltd.
Room 3 & 4, 2nd Floor, Bldg 25, Phase 3.1 Wuhan Optics
Valley International Biopharmaceutical Enterprise Accelerator, No.388,
Gaoxin 2nd RD, East Lake Hi-Tech Development Zone, Wuhan,
430074 Hubei, P.R. China

Contact

Tel. +49 911 655-5225
Mail: service
@de.tuv.com

Date January 25, 2021

Application for: QMS
Certificate No. : SX 2055510-1
Requirement : EN ISO 13485:2016

Dear Madam or Sir,

Enclosed please find the new certificate No. SX 2055510-1 replacing the previous certificate.

With effective date of the new certificate, the previous certificate becomes invalid.

Best regards,

限公司
Co., Ltd

Wenxiang Zhang
Certification body

TÜV Rheinland
LGA Products GmbH

Am Grauen Stein
51105 Köln
Germany

Headquarter

Tillystraße 2
90431 Nuremberg

Phone. +49 911 655 5225
Fax +49 911 655 5226
service@de.tuv.com
www.tuv.com/safety

Dr. Adams®
Laboratories

Distributor Authorisation Letter

Certificate of Authorized Non-Exclusive Distributor

EASYDIAGNOSIS

To whom it may concern,

We, Wuhan EasyDiagnosis Biomedicine Co., Ltd, a corporation with its registered address at Room 3, Factory (3), 1st Floor, Building 25, Phase 3.1 Wuhan Optics Valley International Biopharmaceutical Enterprise Accelerator, No.388, Gaoxin 2nd RD, East Lake Hi-Tech Development Zone, 430074, Wuhan, Hubei P.R China, hereby certify that Dr. Adams Laboratories LTD, with its business address at Unit 21, Grange Way, Colchester, Essex is our non-exclusive distributor in European Countries and the United Kingdom of the products listed as follows:

1. COVID-19 (SARS-CoV-2) Antigen Test Kit
2. COVID-19 Antigen Rapid Test Kit (Saliva/Swabs)

Dr. Adams Laboratories LTD, as our non-exclusive distributor in European Countries and the United Kingdom, will use its best effort to serve customers and provide after-sale services for the aforesaid products.

This Certificate shall commence on December 21, 2021 and shall remain in force for a period of one year unless an earlier termination of the non-exclusive distributorship which will be without further notice.

For further information, please contact zhengxizhen@ediagnosis.cn

Yours sincerely

Wuhan EasyDiagnosis Biomedicine Co., Ltd

Name:

Title: Sales Manager

Date: Dec 22th, 2022

0086-27-65523649
sales@easydiagnosis.com.cn
www.easydiagnosis.com.cn
1st Floor, Building 25, Phase 3.1, Wuhan Optics Valley International Biopharmaceutical Enterprise Park, No 388, Gaoxin 2nd road, East Lake Hi-Tech Development Zone, 430074, Wuhan, Hubei, China

Medicines & Healthcare products
Regulatory Agency

MHRA

Medicines & Healthcare products
Regulatory Agency

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E14 4PU
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+44 (0) 20 3080 6000
gov.uk/mhra

Bioteck Limited
1 The Green
Richmond
TW9 1PL
England, United Kingdom

21 July 2021

Dear **Gloria Yang**

We are pleased to confirm that the application to register or update an existing registration for the following manufacturer, which you submitted on **17 July 2021** has been reviewed:

Application reference: **2021071601208537**

Manufacturer organisation: **Wuhan EasyDiagnosis Biomedicine Co., Ltd.**
Address:
Room 3 & 4, 2nd Floor, Bldg 25, Phase 3.1, Wuhan Optics Valley International Biopharmaceutical Enterprise Accelerator, No. 388, Gaoxin 2nd Road, East Lake Hi-Tech Development Zone
Room 3 & 4, 2nd Floor, Bldg 25, Phase 3.1, Wuhan Optics Valley International Biopharmaceutical Enterprise Accelerator, No. 388, Gaoxin 2nd Road, East Lake Hi-Tech Development Zone
Hubei
Wuhan
430074
China

Manufacturer registration status: **Registered**

Device(s):

Dr. Adams®
Laboratories

GMDN term	Status	MHRA comment
65454 - SARS-CoV-2 antigen IVD, kit, immunochromatographic test (ICT), self-testing	Registered	

Please note this letter does not represent any form of accreditation, certification or approval by the UK Competent Authority.

If you stop placing devices on the market or if you are not complying with the Regulations, you should inform us so that we can amend our records. You should be aware that it is an offence to place on the market UKCA or CE marked devices that do not comply with the regulations.

Please inform us of the following chargeable changes:

1. **company/organisation information e.g. name and address**
2. **additional devices (GMDN code or term)**

Please also use the Devices Online Registration Database (DORS) to tell us of the following changes e.g. removal/ discontinuation of a device (GMDN) or product from your registration record, change of contact person, telephone number and/or email address, for which payment of our statutory fee does not apply.

Please note that the name and address of manufacturer, UK Responsible Person or Authorised Representative (Northern Ireland only) and devices that have been registered will be published on our Public Access Registration Database (PARD).

The account number for your company/organisation is **0000016187.**

Yours sincerely,

Ngozi Onyeukwu
Device registrations service
Devices division
MHRA

Dr. Adams®
Laboratories

Information for use

CE 1434 IVD

Wuhan EasyDiagnosis Biomedicine Co., Ltd.

COVID-19 (SARS-CoV-2) Antigen Test Kit Instruction for Use

- Self-test used on-site or at home
- Please read the instruction for use before use.

[Product name]
COVID-19 (SARS-CoV-2) Antigen Test Kit

[Specification]
1 Test/Kit

[Intended use]
This kit is intended for in vitro qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in nasal swabs from individuals suspected of COVID-19. The kit is intended for layperson use and for people age 7 years or above, children 7-14 years of age should be tested by an adult (over 18 years old). People over 65 years of age should seek help with the test.
COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

[Kit components]
1 Antigen test cassette
1 Antigen extract R1
1 Sample swab
1 Antigen extraction tube (with dropper head)
1 Instruction for use
1 Biohazard waste bag

[Test principle]
This kit employs immunochromatography for detection. The specimen will move forward along the test cassette under capillary action. If the SARS-CoV-2 viral antigen is present, it will be bounded to the colloidal gold-labeled SARS-CoV-2 specific antibodies. The immune complex will be captured by coronavirus monoclonal antibody fixed in the T (Test) line. If the specimen is SARS-CoV-2 positive, both the T (Test) line and C(Control) line will become visible. If the specimen is SARS-CoV-2 negative, the C (Control) line will become visible but the T (Test) line will be invisible. The C line must be visible if the test has been performed correctly.

[Storage & stability]
1. Store at 2℃-30℃, and it is valid for 12 months. DO NOT FREEZE.
2. After the aluminum foil bag is unsealed, the test cassette should be used as soon as possible .

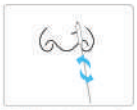
[Preparatory steps]
1. Disinfect the surface where you will open the test kit. Remove and lay out contents of the test kit on a clean, flat surface.
2. Please blow your nose and clear the nostril before taking the test.
3. Wash hands with soap and water. If soap and water are not available, use hand sanitizer. Dry your hand completely before taking the test.
4. You need to prepare a timer or any device with timer function.

[Test methods]
1. Press along the dotted line of the tube stand. Place the extraction tube on the tube stand. Twist the tip to open the Antigen extract R1 container, place the Antigen extract R1 container downward to allow the solution to drip into the extraction tube without touching the edges of extraction tube. Add the entire contents to the extraction tube by squeezing the R1 container.

2. Collect the sample:

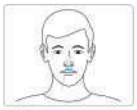
A. Remove the swab from the package. Do not touch the soft end(swab head) with your hands or anything else.

B. Insert the entire soft end of the swab into your nostril (about 1.5-2.0 cm).



C. Slowly rotate the swab, gently press against the inside of your nostril at least 5 times for a total of 15 seconds. Get as much nasal secretion as possible on the soft end of the swab.

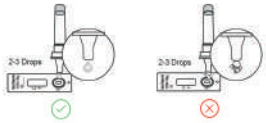
D. Gently remove the swab.



E. Using the same swab, repeat steps B-D in your other nostril with the same end of the swab.

3. Put the swab specimen into the extraction tube, rotate the swab in the liquid for about 10 seconds, and press the swab head against the tube wall to release the specimen in the swab.

4. Squeeze the swab over the head while taking the swab out of the extraction tube to remove as much liquid as possible from the swab. Put the swab after use into the biohazard waste bag.
5. Install the dropper head on the extraction tube, unseal the package and take out the antigen test cassette.
6. Add 2-3 drops into the specimen well of the test cassette, and start the timer. The drops should be liquid not foams/bubbles. If the dorp is foam/bubbles, add another drop.



7. Read the result in 15 minutes. Strong positive results can be reported within 15 minutes, however, negative results must be reported after 15 minutes, and the results after 25 minutes are no longer valid.
8. The antigen test cassette, antigen extract R1, antigen extraction tube (with dropper head) and sample swab after use should be placed in the biohazard waste bag and disposed of with household waste.

9. Wash hands or re-apply hand sanitizer after taking the test.

[Interpretation of test results and instructions for actions]
- Positive result: If both the C line and the T line appear(as shown in the figure below), novel coronavirus antigen has been detected and the result is positive. Look very closely! The T line can be very faint. Any pink/purple line visible here indicates a positive result.

Here are some examples of the colors of T line.

Positive

A positive test result suggests there is currently a suspicion of COVID-19 infection. If your test result is positive, you should immediately contact a doctor/family doctor or the local heath authority and ask for their professional opinions, you should comply with local self-isolation guidelines and have a COVID-19 nucleic acid PCR confirmatory test carried out to confirm the infection.

- Negative result: If there is only a C line (as shown in the figure below), the T line is colorless, indicating that novel coronavirus antigen has not been detected and the result is negative.

CE 1434 IVD
Wuhan EasyDiagnosis Biomedicine Co., Ltd.

Negative

A negative test result does not rule out possibility of infection, an infection may be present even if your test result is negative. You should continue to comply with all applicable rules regarding contact with others and protective measures. In case of suspicion, please repeat the test after 1 - 2 days, as the novel coronavirus may not be detected accurately in all phases of an infection.

- Invalid result: If the C line is not observed, it will be invalid regardless of whether there is T line (as shown in the figure below), and the test should be repeated.

Invalid

An invalid test result is possibly caused by faulty test execution, please repeat the test. If test result is still invalid, contact a doctor or COVID-19 test center for their professional opinions and immediately contact the manufacturer or local supplier.

[Benefits and Limitations]
Benefits:
1. This test kit can be transported and stored at room temperature and is valid for 12 months.
2. This test kit is user-friendly, does not require professional testing equipment and can be used by non-professionals on-site or at home. The results can be observed with the naked eye in only 15 minutes.
3. The test result from this test can help your healthcare provider make informed recommendations for your treatment / care and help limit the spread of COVID-19 to your family and others around you.

Limitation:
1. This test kit is used for in vitro diagnosis only.
2. This test kit is only used to detect human anterior nasal swab extracts. The results of other specimens may be inaccurate.
3. This test kit is only used for qualitative detection and cannot indicate the level of novel coronavirus antigen in the specimen.
4. This test kit is only a clinical auxiliary diagnostic tool. If the result is positive, it is recommended to use other methods for further examination in time and the doctor' s diagnosis shall prevail.

[Clinical performance]
Contrast Results Statistics of Clinically Confirmed/Excluded Results (202 anterior nasal swabs)

Evaluation Reagent	Clinical Confirmed/Excluded Results (RT-PCR CT<32)		Total
	Confirmed	Excluded	
Positive	98	0	98
Negative	4	100	104
Total	102	100	202

Result calculation:
(1) Clinical sensitivity: 96.1%, 95% confidence interval: [90.4%, 98.5%].
(2) Clinical specificity: 100.0%, 95% confidence interval: [96.0%,100.0%].
(3) Clinical accuracy: 98.0%, 95% confidence interval: [95.0%, 99.2%].

[Precautions]
1. The antigen test cassette, antigen extract R1, antigen extraction tube (with dropper head) and sample swab after use should be placed in the biohazard waste bag and disposed of with household waste.
2. Read the instructions carefully before using the kit, and strictly control the reaction time. If you do not follow the instructions, you may get inaccurate results.
3. Protect from moisture, do not open the aluminum foil bag before it is ready for testing. Do not use when the aluminum foil bag is damaged or the test cassette is damp.
4. Please use it within the validity period.
5. Wait all reagents and specimens back to room temperature (15 - 30 ℃) before use.
6. The product contains animal sourced antibodies and the antigen extract R1 contains casein. Do not touch the test strip in the middle of the test cassette and try to avoid touching the liquid of the antigen extract R1.
7. Do not replace the components in this kit with components in other kits.
8. Do not dilute the specimen for testing, otherwise you may get inaccurate results.
9. The kit shall be stored in strict accordance with the conditions specified in this instruction for Use. Please do not store the kit under freezing conditions.
10. The test methods and results must be interpreted in strict accordance with this instruction for Use.

[Index of Symbols]

2℃ 30℃	Temperature Limit		Use-by date
LOT	Batch/Lot code	IVD	In vitro diagnostic medical device
	Manufacturer	REF	Catalogue number
n	Contains sufficient for <N> tests		Consult instructions for use
	Do not re-use	CE 0197	CE Certification
	Date of manufacture	CE 1434	CE Certification
	Do not use if package is damaged	STERILE R	Sterilized using irradiation
EC REP	Authorized representative in the European Community		Biological hazard

[Date of Instruction for use compilation/approval]
V1.0 05.19.2021
V1.1 07.13.2021

[INFORMATION INQUIRIES AND GENERAL INFORMATION]
CE 1434

Wuhan EasyDiagnosis Biomedicine Co., Ltd.
Address: Room 3 & 4, 2nd Floor, Bldg 25, Phase 3.1 Wuhan Optics Valley International Biopharmaceutical Enterprise Accelerator, No.388, Gaoxin 2nd RD, East Lake Hi-Tech Development Zone, 430074 Wuhan, China
Tel: +86(0)27-87808955
Fax: +86(0)27-87808005
WEB: www.mdeasydiagnosis.com
Email: info@ediagnosis.cn

EC REP **Osmunda Medical Technology Service GmbH**
Treskowallee 108, 10318 Berlin, Germany
Tel: 0049-30-81865123

[SWAB INFORMATION]
CE 0197

Shenzhen KangDaAn Biological Technology co., LTD
East- 1, 3rd floor, Building 2, Shunheda factory,Liuxiandong industrial zone, Xili street, Nanshan district, Shenzhen, China

EC REP Name: Share Info Consultant Service LLC Repräsentanzbüro
Address: Heerdter Lohweg 83, 40549 Düsseldorf, Germany

Dr. Adams®
Laboratories

Packaging

Current UK Packaging

New UK Branding from March 2022

Dr. Adams®
Laboratories

Weights and Dimensions

Kit Quantity	Box Size (mm)	Tests Per Carton	Gross Weight
1	150x70x17	400 Tests	10.5kg
5	160x68x45	500 Tests	11.5 Kg
20	205x125x75	1000 Tests	15.7Kg

Kit Quantity	Carton Size (mm)	Pallet Quantity	Pallet Weight
1	620x470x310	24 Cartons	252Kg
5	490x365x340	24 Cartons	276Kg
20	645x425x415	20 Cartons	314kg

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Buy with 100% confidence.

We are fully compliant with UK & EU Government regulations

We deliver optimum value to our clients
by contracting directly with all our
manufacturers to provide you with reduced
lead times and unmatched supply.

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Unit 21, Grange Way Business Park |Grange Way | Colchester, Essex CO2 8HF