

# Safety Data Sheet

## (SDS)

**Samples Name:** Menstrual Cup/Disc

**Lot No.:** /

**Client Name:** Xi'an Furuize Biotechnology Co., Ltd.

**Address:** No. 11, Tangyan South Road, High-Tech Zone, Xi'an, Shaanxi, China

**Post Code:** 710000

**Summary:** As per request, the contents and formats of the SDS are prepared in accordance with European Commission Regulation (EC) No 1907/2006, Regulation (EC) No 1272/2008 and Regulation (EU) No 2020/878.

Remark: The SDS is prepared based on the information provided by client.

APPROVED BY:



Technology Manager



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Shenzhen Huipu Testing Technology Co., Ltd.

Add: Unit 2, Building B3, Sunshine Garden, Guanghua Community, Jihua Street, Longgang District, Shenzhen, Guangdong, China

Tel: 86-0755-2309 2593

86-13117584928

Email: huiputest@163.com

## SECTION 1: Identification of the substance/mixture and of the company/undertaking

### 1.1 Product Identification

**Samples Name:** Menstrual Cup/Disc

**Trade name:** /

**UFI:** No detailed information available

### 1.2 Relevant usage information and prohibited uses of the substance/mixture

**Purpose of the substance/mixture:** Female physiological products

### 1.3 Supplier details in the safety technical manual

**Manufacturer/Supplier:** Xi'an Furuize Biotechnology Co., Ltd.

**Address:** No. 11, Tangyan South Road, High-Tech Zone, Xi'an, Shaanxi, China

**Contact Person:** Frank Wang

**Tel:** +86 13389223500

**Email:** frank@furuize.com.cn

**1.4 Sole representative/EU contact person:** No relevant details available

## Section 2 - Hazards Identification

### 2.1 Hazard categories of substances or mixtures

**Classification according to Regulation (EC) No 1272/2008 [EU-GHS/CLP] and its amendments**

**Classification:** The product is not classified as hazardous according to the CLP regulation.

**Label elements, including precautionary statements**

The product does not need to be labelled in accordance with EC directives or respective national laws.

**Pictogram(s):** No pictogram is used.

**Signal Word:** No signal word is used.

**Hazard Statement:** No hazard statement.

**Waste disposal:** P501 Dispose of contents/containers in accordance with local/regional/national/international regulations

### 2.2 Other hazards:

Evaluation results of PBT (persistent, bioaccumulative, and toxic substances) and vPvB (highly persistent and bioaccumulative substances)

PBT (persistent, bioaccumulative, and toxic substances): Not applicable

vPvB (high persistence and high bioaccumulation substances): Not applicable

## Section 3 –Composition/Information on Ingredients

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### 3.1 Substances

### 3.2 Mixtures

Description: A mixture composed of the following components containing harmless additives.

Chemical Name	Composition (in% by weight)	CAS No.
Thermoplastic polyurethanes	100	1211-14-9

## Section 4 - First Aid Measures

### 4.1 Essentials of emergency measures

General instructions: Immediately remove the clothes stained with the product.

Inhalation: Provide fresh air and ensure that a doctor is called.

If the patient is not clear, please let them lie on their side for easy movement.

Skin contact: Immediately rinse thoroughly with water and soap.

Eye contact: Open your eyes and rinse under running water for several minutes. If the symptoms continue, consult a doctor.

Ingestion: If symptoms persist, consult a doctor.

**4.2 Most important acute and chronic symptoms and their effects:** No detailed information available.

**4.3 Symptoms that require timely medical treatment and special treatment:** No detailed information available.

## Section 5 - Fire Fighting Measures

### 5.1 Fire extinguishing agents

**Suitable fire extinguishing agent:** Use fire extinguishing measures suitable for the surrounding environment.

**5.2 Special hazards of substances or mixtures:** No detailed information available.

### 5.3 Information for firefighters

Protective equipment: No special measures required.

## Section 6 –Accidental Release Measures

**6.1 Personal protective measures, protective equipment, and emergency response procedures:** No requirements.

**6.2 Environmental protection measures:** Do not let the product come into contact with the sewage system or any water source. If it seeps into the water source or sewage system, please notify the relevant authorities. Dilute with a large amount of water. Do not allow it to enter the sewer/water surface or groundwater.

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### 6.3 Methods and materials for containment and removal of leaks:

Absorb liquid bonding materials (sand particles, diatomaceous earth, acidic adhesives, universal adhesives, sawdust). Dispose of contaminated materials according to Section 13.

Ensure that there is sufficient ventilation.

### 6.4 Refer to other parts:

Please refer to Section 7 for information on safe handling.

For information on personal protective equipment, see Section 8.

Please refer to Section 13 for information on disposal

## Section 7 - Handling and Storage

**7.1 Preventive measures for safe operation and disposal:** Ensure that the workplace has good ventilation/exhaust devices. Prevent the formation of aerosols. Please refer to Section 8 for general occupational health measures.

Information on fire and explosion prevention: No special measures are required.

### 7.2 Safe storage conditions, including any incompatibilities

Requirements to be met for storage and containers: There are no special requirements.

Information about storage in shared storage facilities: The storage area must be kept away from food. The storage area must be kept away from water sources.

More information about storage conditions: Seal the container.

### 7.3 Specific end use: No detailed information available.

## Section 8 - Exposure Controls, Personal Protection

### 8.1. Control parameters

Ingredients that require limit monitoring in the workplace: Not applicable

Regulatory Information AGW (D): TRGS 900

Derived no impact concentration values without relevant detailed information

Estimated concentration values with no significant impact No relevant detailed information

Additional information: A valid list during the production period will be used as a basis.

### 8.2 Exposure Control Based on the ingredient information listed in Part 3, it is recommended to adopt the following safety measures in occupational exposure control

Appropriate technical control: stay away from food, beverages, and feed. Immediately remove all unclean and contaminated clothing. Please clean your hands before rest and after work. Avoid contact with eyes and skin. Please refer to Part 7 for information on technical facility design.

Personal protective measures, such as personal protective equipment

Respiratory system protection:

(Continued from page 3)

If you have had brief contact or in low pollution situations, please use a respiratory filtration device. If you have been in deep or prolonged contact, please use a separate respiratory protective device.

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Hand protection:



Eye/face protection: Sealed goggles

Skin and body protection: Protective work clothes

Thermal hazard: Not required under normal use.

Environmental exposure control: Control measures must comply with environmental protection regulations.

## Section 9 - Physical and Chemical Properties

### 9.1 Information about basic physical and chemical characteristics

Appearance: Solid

Color: White translucent

Odor: Odorless

Melting point/freezing point: Norelevantdetailedinformation available

Boiling point or initial boiling point and boiling range: No relevant detailed information available

Flammability: No relevant detailed information available

Explosion limit

Lower limit: No relevant detailed information available

Upper limit: No relevant details available

Flash point: No relevant detailed information available

Self ignition temperature: No relevant detailed information available

Decomposition temperature: No detailed information available

pH: No relevant details available

Dynamic viscosity: No detailed information available

Solubility : Water: No detailed information available

n-octanol/water partition coefficient (logarithmic value): No relevant detailed information available

Vapor pressure: No relevant detailed information available

Density/relative density

Density: No relevant detailed information available

Relative density: No relevant detailed information available

Relative vapor density: No detailed information available

## Section 10 - Stability and Reactivity

10.1 Reactivity: No detailed information available.

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10.2 chemical stability: No relevant details.

10.3 Possibility of hazardous reactions: There are no known hazardous reactions.

10.4 Conditions to avoid: No relevant detailed information available.

10.5 Incompatible substances: No detailed information available.

10.6 Hazardous decomposition products: Unknown hazardous decomposition products.

## Section 11 - Toxicological Information

11.1 Information on hazard categories defined in EU Regulation (EC) No. 1272/2008

Acute toxicity: No detailed information available.

Skin corrosion/irritation: No detailed information available.

Serious eye damage/eye irritation: No detailed information available.

Respiratory or skin allergies: No detailed information available.

germ cell mutagenicity: according to the existing data, it does not meet the classification criteria.

Carcinogenicity: According to existing data, it does not meet the classification criteria.

reproductive toxicity: according to the available data, the classification criteria are not met.

Specific target organ systemic toxicity - single exposure: According to existing data, it does not meet the classification criteria.

Specific target organ systemic toxicity - repeated exposure: Based on existing data, does not meet classification criteria.

Inhalation hazard: According to existing data, it does not meet the classification criteria.

11.2 Information on other hazards

Endocrine disrupting properties: No detailed information available.

Other information: No known other relevant information on adverse health effects.

## Section 12 - Ecological Information

12.1 Ecological toxicity

Aquatic toxicity: No detailed information available.

12.2 Persistence and degradability: No detailed information available.

12.3 Potential bioaccumulation: No detailed information available.

12.4 Soil mobility: No detailed information available.

12.5 PBT (persistent, bioaccumulative, and toxic substances) and vPvB (highly persistent and bioaccumulative substances) evaluation results

PBT (persistent, bioaccumulative, and toxic substances): Not applicable

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vPvB (high persistence and high bioaccumulation substances): Not applicable

12.6 Endocrine disrupting properties: This product does not contain substances with endocrine disrupting properties.

12.7 Other side effects: No detailed information available.

## Section 13 - Disposal Considerations

### 13.1 Waste disposal methods

Suggestion: Do not dispose of this product together with household waste. Do not let the product come into contact with the sewage system.

Contaminated containers and packaging:

Suggestion: It must be discarded according to official regulations.

## Section 14 - Transport Information

### 14.1 United Nations dangerous goods number (UN 号) : No Data

ADR/RID/ADN, IMDG, IATA                      Unclassified

### 14.2 UN Appropriate shipping name

· ADR/RID/ADN :                                      Unclassified

### 14.3 Transportation hazard grade

· ADR/RID/ADN, IMDG, IATA :                      Unclassified

### 14.4 PACKING GROUP

ADR/RID/ADN, IMDG, IATA :                      Unclassified

### 14.5 Environmental hazards:

· Marine pollutants:                                      No relevant details available.

Special marking (ADR/RID/ADN):                      No relevant details available.

Special marking (IATA):                                      No relevant details available.

14.6 Special precautions for users                      No relevant details available.

· Danger coding:                                      No relevant details available.

· EMS number:                                      No relevant details available.

Stowage Category                                      No relevant details available.

## Section 15 - Regulatory Information

### 15.1 Safety, health care and environmental regulations/laws for corresponding pure substances or mixtures.

EU Directive 2012/18/EU

Appendix 1 Dangerous substances These ingredients are not listed on the list.

Seveso category E2

Qualifying quantity (tonnes) for the application of lower-tier requirements : Not applicable

Qualifying quantity (tonnes) for the application of upper-tier requirements : Not applicable

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EU Regulation (EU) 2019/1021 Persistent Organic Pollutants (POPs): None of these components are listed on the list.

EU Regulation (EU) 649/2012: None of these ingredients are listed on the list.

EU Regulation (EU) 2019/1148

Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3)): None of these ingredients are listed on the list.

Annex II - REPORTABLE EXPLOSIVES PRECURSORS: None of these ingredients are listed on the list.

EU Regulation (EC) 273/2004 Drug Precursors:None of these ingredients are listed on the list.

EU Regulation (EC) 111/2005 Monitoring Rules of Drug Precursor Trade between Community and Third Countries;None of these ingredients are listed on the list.

Annex I of EU Regulation (EC) 1005/2009 on Substances that Deplete the Ozone Layer:None of these ingredients are listed on the list.

Other regulations, restrictions and prohibitions

Candidate List of Substances of High Concern in Appendix XIV of REACH Regulation for Authorized Consideration (17/1/2023): No ingredients are listed.

Annex XVII Restricted Substances of EU Regulation REACH (13/12/2021)

Annex XIV of EU regulation REACH authorizes substances (8/4/2022): No ingredients are listed.

15.2 Safety evaluation of chemical substances: No safety evaluation of chemical substances has been conducted.

## Section 16 - Additional Information

The above information is based on the data of which we are aware and is believed to be correct as of the data hereof. Since this information may be applied under conditions beyond our control and with which may be unfamiliar and since data made available subsequent to the data hereof may suggest modifications of the information, we do not assume any responsibility for the results of its use. This information is furnished upon condition that the person receiving it shall make his own determination of the suitability of the material for his particular purpose.

\*\*\*\*\*End of SDS\*\*\*\*\*

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# Test Report

Report No.: HLF21001504EA

Date: Jan 11, 2021

Page 1 of 15

**Applicant** : Xi'an Furuize Biotechnology Co., Ltd.

**Address** : Room 11131 , Building 3,i Duhui, No.11 ,Tangyan South Road ,Zhangba Street Office , High-tech Zone ,Xi'an City, Shaanxi, China.

**The following sample(s) and sample information was/were submitted and identified by/on behalf of the client**

Sample Name : Menstrual cup

Sample Model : 014

Sample Lot : 1225

Sample Received Date : Jan 5, 2021

Test Completed Date : Jan 11, 2021


Test Requested : As specified by client, to screen on Jun 16, 2020 the 209 Substances of Very High Concern (SVHC) under the regulation (EC) No 1907/2006 of REACH for the submitted samples .

Test Method : In-House method – Analyzed by ICP-OES, PLM, UV-VIS, LC-MS, GC-MS and colorimetric method.

Test Results : Refer to the next page(s).

Test Conclusion : According to the specified scope and evaluation screening, the test results of SVHC are $\leq 0.1\%$ (w/w) in the submitted sample.	PASS
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Reviewed by:

  
\_\_\_\_\_  
Lab Senior Engineer

Authorized Signature:

  
\_\_\_\_\_  
Technology Manager

In no circumstances shall the Company's responsibility extend beyond inspection, testing and reporting upon the samples actually drawn from the bulk and inspected, tested and surveyed by the Company and any inference to be drawn from the results of such inspection or survey or testing shall be entirely in the discretion and at the sole and exclusive responsibility of the Principal. This test report cannot be reproduced except in full.



FLION TESTING TECHNOLOGIES

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Tel : 86-0755-2724 8885 Fax : 86-0755-2746 0090 Http://www.cnftt.com

**REACH SVHCs Test Results:**

No.	Test Item	CAS No.	EC No.	RL(%)	Result (%)
1	4,4'-Diaminodiphenylmethane	101-77-9	202-974-4	0.05	N.D.
2	5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene)	81-15-2	201-329-4	0.05	N.D.
3	Alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins)	85535-84-8	287-476-5	0.05	N.D.
4	Anthracene	120-12-7	204-371-1	0.05	N.D.
5	Benzyl butyl phthalate (BBP)	85-68-7	201-622-7	0.05	N.D.
6	Bis (2-ethyl(hexyl)phthalate) (DEHP)	117-81-7	204-211-0	0.05	N.D.
7	Bis(tributyltin)oxide (TBTO)*	56-35-9	200-268-0	0.05	N.D.
8	Cobalt dichloride*	7646-79-9	231-589-4	0.05	N.D.
9	Diarsenic pentaoxide*	1303-28-2	215-116-9	0.05	N.D.
10	Diarsenic trioxide*	1327-53-3	215-481-4	0.05	N.D.
11	Dibutyl phthalate (DBP)	84-74-2	201-557-4	0.05	N.D.
12	Hexabromocyclododecane (HBCDD) and all major diastereoisomers identified: α-HBCDD β-HBCDD γ-HBCDD	25637-99-4 3194-55-6 (134237-51-7 134237-50-6 134237-52-8)	247-148-4 221-695-9	0.05	N.D.
13	Lead hydrogen arsenate*	7784-40-9	232-064-2	0.05	N.D.
14	Sodium dichromate*	10588-01-9 7789-12-0	234-190-3	0.05	N.D.
15	Triethyl arsenate*	15606-95-8	427-700-2	0.05	N.D.
16	2,4-Dinitrotoluene	121-14-2	204-450-0	0.05	N.D.
17	Acrylamide	79-06-1	201-173-7	0.05	N.D.

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Tel : 86-0755-2724 8885 Fax : 86-0755-2746 0090 Http://www.cnfit.com

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**ACM**

# Certificate of Registration

This is to certify that the  
Quality Management System  
of

**Xi'an Furuize Biotechnology Co.,Ltd. Dongguan Branch**  
Unified social credit code: 91441900MA7EUK553H  
Registered Address  
Room 201, Building 1, No.7-1, Lingnan 3rd Road, Huangdong  
Fenggang Town, Dongguan, Guangdong  
Office & Production Address  
Room 201, Building 1, No.7-1, Lingnan 3rd Road, Huangdong  
Fenggang Town, Dongguan, Guangdong, China

Has been independently assessed and is  
compliant with the requirements of:

**ISO 9001:2015**

For the following scope of activities:

**Production of Menstrual Cup and Cup Steamer**

Certificate Number: 22ACM16256Q

Date of initial registration 13/04/2022  
Certificate expiry 12/04/2025  
(subject to the company maintaining its system to the required standard)



AUTHORISED SIGNATORY  
Date of this certificate 13/04/2022, V1

During validity period of the certificate a surveillance audit should be carried out once within each 12 months. The label should be pasted on specified position of right side of the certificate then it is valid. The certificate can be checked out at China CNCA website([www.cnca.gov.cn](http://www.cnca.gov.cn)) and ACM UK website([www.acmcert.com](http://www.acmcert.com)).



ACM-CCAS Limited, Unit 5 Merus Court, Meridian Business Park, Leicester, LE19 1RJ, UK  
Local Office-ACM (CHINA) LIMITED, Rm B201, No 352, Waihuan Road, Minhang District, Shanghai 201199, China  
T: +86 21 64305860 F: +86 21 64881096 W: [www.acmcert.com.cn](http://www.acmcert.com.cn) E: [info@acmcert.com.cn](mailto:info@acmcert.com.cn)

0245



**United States**  
**ENVIRONMENTAL PROTECTION AGENCY (EPA)**  
**Washington, DC 20460**  
**Registration of Pesticide-Producing and Device-Producing Establishments**  
Section 7, Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. sec. 136e)

This document indicated that:

**XI'AN FURUIZE BIOTECHNOLOGY CO., LTD.**

has registered with U.S. Environment Protection Agency in accordance with Section 7, FIFRA (Federal Insecticide, Fungicide and Rodenticide Act) as amended.

The following establishment information has been activated:

Establishment Number: **100258-CHN-1**

Establishment Company: **XI'AN FURUIZE BIOTECHNOLOGY CO., LTD.**

Establishment Address: **Room 11131, Building 3, I Duhui, No.11, Tangyan South Road, Zhangba Street Office, High-tech Zone, Xian City, Shaanxi, China**

After the initial report is submitted, each facility that produces pesticides or devices must submit a report to EPA annually, on or before March 1<sup>st</sup>, even when no products are produced or distributed. Failure to file an initial or annual production report is a violation of FIFRA, and may result in termination of the establishment's registration, civil penalties.

This document does not warrant compliance with all other applicable laws and regulations in the United States. The U.S. Environment Protection Agency does not issue a certification of registration, nor does the U.S. Environment Protection Agency recognize a certificate of registration. SATISFY TECH AND SERVICE LLC is not affiliated with the U.S Environment Protection Agency.

Establishment information was listed in EPA Establishment database:

<https://www.epa.gov/compliance/national-list-active-epa-registered-foreign-and-domestic-pesticide-andor-device> ,or contact EPA.

Assigned Date: October 8, 2021



中国认可  
国际互认  
检测  
TESTING  
CNAS L30066

# Test Report

**Report Number:** SSMT-R-2020-03009-01B

**Sample Name:** menstrual cup

**Study Title:** In Vitro Cytotoxicity Test

**Standard:** ISO 10993-5:2009

GB/T 16886.5-2017

## Test facility

Jiangsu Science Standard Medical  
Testing Co., Ltd.

C4 Building, No.9 Changyang Road, Wujin  
District, Changzhou, Jiangsu, China

## Sponsor

Xi'an Furuize Biotechnology Co., Ltd.

Room 11131 , Building 3,i Duhui, No.11 ,Tangyan  
South Road ,Zhangba Street Office ,High-tech  
Zone ,Xi'an City, Shaanxi, China.

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### JiangSu Science Standard Medical Testing Co., Ltd.

C4 Building, No.9 Changyang Road, Wujin District, Changzhou, Jiangsu, China 213161 Tel:(86-519-83587899) Fax:(86-519-83587899) www.jssmt.com

Document No.: SHT-ASS-A11 Version 2.0

Page 1 of 10



**Fiscal Year 2024**

## **CERTIFICATION OF REGISTRATION**

**THIS CERTIFIES THAT:**

**Applicant:** Xi'an Furuize Biotechnology Co., Ltd.  
**Address:** Room 11131, Building 3, I Duhui, No.11 ,Tangyan South Road ,Zhangba Street Office ,High-Tech Zone Xi'an Shaanxi, CN 710065

**Owner Operator Number:** 10061640

**Has completed the FDA Establishment Registration and Device Listing with the US Food & Drug. Owner/Operator Number:: 10061640 Device Listing#: See annex**

Agent will confirm that such registration remains effective upon request and presentation of this certificate until the end of the calendar year stated above, unless said registration is terminated after issuance of this certificate. Agent makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. Agent assumes no liability to any person or entity in connection with the foregoing.

Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding." The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration, Agent is not affiliated with the U.S. Food and Drug Administration.



A handwritten signature in black ink, appearing to read "Amy", written over a horizontal line.

Executive Director

Issued: January 1, 2024

CERT202001010001

Expiration Date: DECEMBER 31, 2024



# CERTIFICATE

N. CN22 – 08902H

This is to certify that the Quality Management System of Medical Devices of

## **Xi'an Furuize Biotechnology Co.,Ltd. Dongguan Branch**

**Unified social credit code:** 91441900MA7EUK553H

**Registered Address**

Room 201, Building 1, No.7-1, Lingnan 3rd Road, Huangdong, Fenggang Town  
Dongguan, Guangdong

**Office & Production Address**

Room 201, Building 1, No.7-1, Lingnan 3rd Road, Huangdong, Fenggang Town  
Dongguan, Guangdong, China

Has been independently assessed and found in conformance with the standard

## **ISO 13485:2016**

For the following scope of activities:

### **Production of Menstrual Cup and Cup Steamer**

**Category:** A.1.1, A.1.2

For further and updated information regarding any changes in the status of this certification please contact via phone under +355696037861 / +39 0296368458 or via email to [info@axe-register.com](mailto:info@axe-register.com) or verify directly on the website [www.axe-register.com](http://www.axe-register.com) by using the organization name or the certificate number.

The validity of this certificate is subject to periodic yearly surveillance audit and triennial review of the entire management system of the certified organization.

<b>Date of first registration</b>	<b>30/04/2022</b>
<b>Date of this certificate</b>	<b>30/04/2022</b>
<b>Date of expiry</b>	<b>29/04/2025</b>



On behalf of the Certification Body

**AXE REGISTER Ltd**

*Antonio Lavda*  
Technical Director



**CS 007 26.02.18**

Signatory of EA/MLA, Mutual Recognition Agreements

During validity period of the certificate a surveillance audit should be carried out once within each 12 months. The label should be pasted on specified position of right side of the certificate then it is valid. The certificate can be checked out at CNCA website ([www.cnca.gov.cn](http://www.cnca.gov.cn)).



**AXE REGISTER**

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