

Report Number: MIC-ASR213651

Audit Date : 11 May, 2021

This report is issued by Focus Technology Co., Ltd. (Made-in-China.com) and the supervising inspectorate (Bureau Veritas) to confirm that:

Company Name : Zhejiang Leadtop Pharmaceutical Machinery Co., Ltd.
浙江亿拓制药机械有限公司
Showroom : <https://pharma-machinery.en.made-in-china.com>
Address : Development Zone of Ruian Economic Development Zone, Wenzhou City, Zhejiang Province, China
Product : Pharmaceutical Machinery, Pharmaceutical Packaging Material, Drying Machine, Granulating

has been on site audited for the Following Scope of Activity

1. General Information
2. Foreign Trade Capacity
3. Product Research & Development Capacity
4. Management System and Product Certification
5. Production Capacity & Quality Control
---the audit content of this part relates only to its associated enterprise
6. Working Environment
7. Energy Saving and Emission Reduction
8. Photos



General Comments:

Zhejiang Leadtop Pharmaceutical Machinery Co., Ltd. is a manufacturer with 26 employees; it was established in 2012, located in Development Zone of Ruian Economic Development Zone, Wenzhou City, Zhejiang Province, China. The company occupies an area of about 600 square meters. Zhejiang Leadtop Pharmaceutical Machinery Co., Ltd. has successful foreign trading experience in North America, South America, Europe, Southeast Asia/ Mideast, Africa, East Asia(Japan/ South Korea), Australia. The company has a associated company (Wenzhou Mintech Machinery Technology Co.,Ltd).

ZhangLi

Sign for and on behalf of
Bureau Veritas



SUPPLIER ASSESSMENT REPORT

Audited Company	Zhejiang Leadtop Pharmaceutical Machinery Co., Ltd. 浙江亿拓制药机械有限公司		
Audited Site:	Development Zone of Ruian Economic Development Zone, Wenzhou City, Zhejiang Province, China		
Consigner of Assessment	Made-in-China.com		
Audit Type	<input type="checkbox"/> Initial Audit <input checked="" type="checkbox"/> Re-audit		
Audit Date	11 May, 2021	Verify Report	http://www.bvcerchina.cn
Auditor	Wenjing Shi	Reviewed by	Rosy Cheng

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Part A: General Information

Section 1: Company Overview

1.1 Legal Validity			
Does the company have a valid business license?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Others	Registration Number	91330381589029104H
Year of established	06 Jan., 2012	Valid Date	05 Jan., 2032
Registered address	Development Zone of Ruian Economic Development Zone, Wenzhou City, Zhejiang Province, China		
Actual address	Development Zone of Ruian Economic Development Zone, Wenzhou City, Zhejiang Province, China		
Does the company in abnormal operation status list of industrial and commercial bureau?	No		
Registered capital	RMB 10000000		
Name of legal representative	Ms. Jing Jiang		
Business scope	General items: mechanical equipment sales; Auto parts retail; Auto parts wholesale; Retail of motorcycles and spare parts; Wholesale of motorcycles and spare parts; Sales of building materials; Sales of building decoration materials; General merchandise sales; Sales of knitwear; Sales of electronic products; Sales of office supplies; Sales of household appliances; Electrical accessories sales; Sales of chemical products (excluding licensed chemical products); Clothing retail; Clothing wholesale; Retail of shoes and hats; Shoes and hats wholesale; Sales of leather products; Luggage sales; Toy sales; Hardware products retail; Hardware products wholesale; Sales of metal materials; Sanitary ware sales; Sales of Arts and crafts and ceremonial products (except ivory and its products); Retail of Arts and crafts and collectibles (except ivory and its products); Sales of communication equipment; Computer hardware and software and auxiliary equipment retail; Computer hardware and software and auxiliary equipment wholesale; Sales of class I medical devices; The second category of medical device sales (except for the items that need to be approved according to law, the business activities shall be carried out independently according to law with the business license). Licensing items: import and export of goods; Technology import and export (for projects that need to be approved according to law, business activities can only be carried out with the approval of relevant departments, and the specific business projects shall be subject to the approval results).		
1.2 Basic Information			
Contact person	Ms. Hannah		
Phone number	0086-15867716281	Fax number	0086-0577-65158977
URL/Web address	https://pharma-machinery.en.made-in-china.com		
Company type	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Trading Company <input checked="" type="checkbox"/> Combined <input type="checkbox"/> Group Corporation		
Type of ownership	<input checked="" type="checkbox"/> Limited Company <input type="checkbox"/> Public Company <input type="checkbox"/> Foreign joint venture <input type="checkbox"/> State-Owned <input type="checkbox"/> Private Owner <input type="checkbox"/> Wholly foreign-owned enterprises		

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Associated company	<ul style="list-style-type: none"> ■ Audited company : Zhejiang Leadtop Pharmaceutical Machinery Co., Ltd. ■ Associated company: Wenzhou Mintech Machinery Technology Co.,Ltd ■ The relationship of two companies: <input checked="" type="checkbox"/> Shareholders have 100% shares in audited company and 51% shares in associated company
Products manufactured / sold scope	Pharmaceutical Machinery, Pharmaceutical Packaging Material, Drying Machine, Granulating
1.3 Company Building Information	
<p>According to:</p> <div style="display: flex; justify-content: space-between;"> <div> <input type="checkbox"/> Land certificate <input type="checkbox"/> Lease agreement </div> <div> <input type="checkbox"/> Real estate certificate <input checked="" type="checkbox"/> Observation Estimated on site </div> </div> <p> The company area 600 square meters The land occupies 600 square meters. The offices occupy 600 square meters. The workshops occupy Nil square meters. </p>	

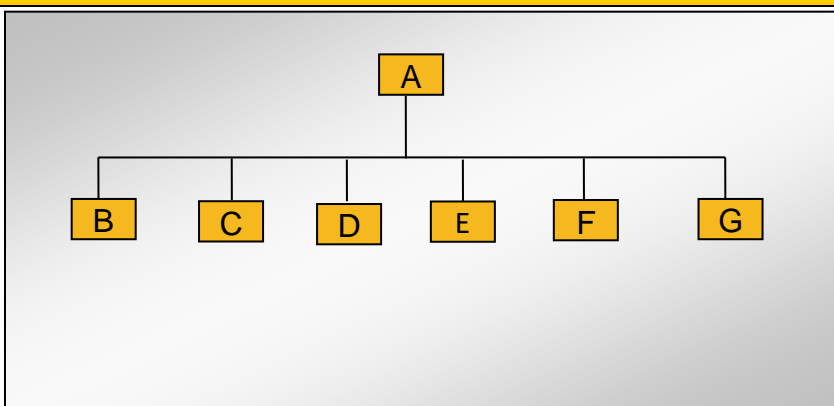
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Section 2: Human Resources

2.1 Company Chart



2.2 Explanation of Code and Employee Details

Code	Department	Number of employees
A	General Manager	1
B	E-Commerce Department	2
C	Sales Department	13
D	Finance Department	2
E	Logistics Department	2
F	Research and Development Department	2
G	Purchasing Department	4
Number in total:		26

2.3 Key Staff

Title	Full name	Education	Working experience for this trade / total experience
Sales Manager	Ms. Hannah	University	4/4 Years

Remark: Above information of key staff was based on interview with company representative.



Part B: Foreign Trade Capacity

Section 1: Export Overall Situation

1.1 Export Overall Situation	
Does the company have a valid Import and Export license?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
The import and export enterprise code.	91330381589029104H
The number of foreign trading staff with relevant trading experience.	<input type="checkbox"/> within 1 year staff <input checked="" type="checkbox"/> 1-5 years 5 staffs <input checked="" type="checkbox"/> 6-10 years 4 staffs <input checked="" type="checkbox"/> over 10 years 4 staffs Total 13 staffs
The language freely used by foreign trade staff	<input checked="" type="checkbox"/> English <input type="checkbox"/> others:
Annual revenue of previous year	Confidential
Annual export revenue of previous year	Confidential
Estimated export revenue for this year.	Confidential
Overseas agent / branch	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Nearest port	Ningbo Port, Shanghai Port
Acceptable quotation terms	<input checked="" type="checkbox"/> FOB <input checked="" type="checkbox"/> CIF <input checked="" type="checkbox"/> CFR
Acceptable payment terms	<input checked="" type="checkbox"/> LC <input checked="" type="checkbox"/> T/T <input checked="" type="checkbox"/> D/P <input checked="" type="checkbox"/> PayPal <input checked="" type="checkbox"/> Western Union <input type="checkbox"/> Small-amount payment
Average lead time (Peak Season)	<input type="checkbox"/> within 15 workday <input checked="" type="checkbox"/> one month <input type="checkbox"/> 2-3 months <input type="checkbox"/> 4-6 months <input type="checkbox"/> 6-12 months <input type="checkbox"/> more time
Average lead time (Off Season)	<input type="checkbox"/> within 15 workday <input checked="" type="checkbox"/> one month <input type="checkbox"/> 2-3 months <input type="checkbox"/> 4-6 months <input type="checkbox"/> 6-12 months <input type="checkbox"/> more time

Section 2: Export Business Capacity

2.1 Market Distribution (please list top three areas)		
Market	Main Product	Main client
<input checked="" type="checkbox"/> North America	Pharmaceutical Machinery, Pharmaceutical Packaging Material, Drying Machine, Granulating	Confidential
<input checked="" type="checkbox"/> South America	Pharmaceutical Machinery, Pharmaceutical Packaging Material, Drying Machine, Granulating	Confidential
<input checked="" type="checkbox"/> Europe	Pharmaceutical Machinery, Pharmaceutical Packaging Material, Drying Machine, Granulating	Confidential
<input checked="" type="checkbox"/> Southeast Asia/ Mideast	Pharmaceutical Machinery, Pharmaceutical Packaging Material, Drying Machine, Granulating	Confidential
<input checked="" type="checkbox"/> Africa	Pharmaceutical Machinery, Pharmaceutical Packaging Material, Drying Machine, Granulating	Confidential
<input checked="" type="checkbox"/> East Asia (Japan/ South Korea)	Pharmaceutical Machinery, Pharmaceutical Packaging Material, Drying Machine, Granulating	Confidential
<input checked="" type="checkbox"/> Australia	Pharmaceutical Machinery, Pharmaceutical Packaging Material, Drying Machine, Granulating	Confidential

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Section 3: Supplier Management

3.1 Supplier Management		
Item	Content	Observations /Comments
1	Does the company establish and implement an effective suppliers' assessment procedure?	<input checked="" type="checkbox"/> Have the written procedures and followed records <input type="checkbox"/> Have the written procedures but no records <input type="checkbox"/> Have relevant records without written procedure <input type="checkbox"/> No written procedures or followed records <input type="checkbox"/> Other
2	Does the company have an updated list of approved suppliers?	<input type="checkbox"/> The approved suppliers list was updated in _____ <input type="checkbox"/> Have the written suppliers without approved signature or date. <input checked="" type="checkbox"/> Provided some suppliers names <input type="checkbox"/> No approved suppliers list <input type="checkbox"/> Other

Section 4: After-sales Service Capacity

4.1 After-sales Service Capacity		
Item	Content	Observations /Comments
1	Is there a procedure to conduct random product inspection after final packaging in place?	<input checked="" type="checkbox"/> Have clear standards and written inspection records <input type="checkbox"/> No written standards but had inspection reports <input type="checkbox"/> Have the procedures but no inspection records <input type="checkbox"/> It's not necessary to carry out the inspection <input type="checkbox"/> Other
2	Is there a clear procedure for handling customer complaints?	<input checked="" type="checkbox"/> Has the clear procedure and followed records <input type="checkbox"/> Has the procedure but no written records. <input type="checkbox"/> No written procedures or records. <input type="checkbox"/> Other
3	Can the finished/packaged product be traced by lot identification to the appropriate raw materials test reports?	<input type="checkbox"/> Have the procedures to trace the raw materials. <input checked="" type="checkbox"/> Can trace main materials <input type="checkbox"/> Can trace production date. <input type="checkbox"/> Can't trace products <input type="checkbox"/> Other
4	Are corrective & preventive actions mechanism established and implemented effectively (including the suppliers/ sub-contractors control, incoming inspection, process control, final inspection and customer complaint)?	<input checked="" type="checkbox"/> Has the clear procedure and followed records <input type="checkbox"/> Has the procedure but no written records. <input type="checkbox"/> No written procedures or records. <input type="checkbox"/> Other



Part C: Product Research & Development Capacity

1.1 Product Research & Development Capacity	
The amount of R&D and relevant working experience.	<input type="checkbox"/> within 1year staff <input type="checkbox"/> 1-5 years staff <input checked="" type="checkbox"/> 6-10 years 1 staff <input checked="" type="checkbox"/> over 10 years 1 staff Total 2 engineers
What is the main job responsibility for R&D engineers?	Technology engineers were responsible for confirming customer's request, providing technical support for production and after-sales service.
Is there any relevant design input, output, review, verification and validation documentation available for auditor to review?	Yes
Is there any special software or instrument used by the R&D staffs during the design process of new products? If yes, please list the main software or instrument.	Yes, CAD, Solidworks, UG
Does the company have an effective design change control procedure in place?	Yes
Please list the patent certificates and qualification license.	Nil



Part D: Management System and Product Certification

1.1 Management System and Product Certification	
Management system certification	<input checked="" type="checkbox"/> ISO9001:2015 certificate Certificate Name: ISO9001:2015 certificate NO.: 20220Q20662R0S Issued by: ZHEJIANG QUANPIN CERTIFICATION CO., LTD. Issued Date: 17 Aug., 2020 Valid Until: 16 Aug., 2023 Scope: N/A
Product certification	<input checked="" type="checkbox"/> CE Certificate Name: CE NO.: M.2020.206.C61807 Product Name: Blister Packing Machine Model: N/A Standard: N/A Issued by: UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co. Issue Date: 25 Jan., 2021 Certificate Name: CE NO.: M.2020.206.C61809 Product Name: Table Press Machine Model: N/A Standard: N/A Issued by: UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co. Issue Date: 25 Jan., 2021 Certificate Name: CE NO.: M.2020.206.C61805 Product Name: Table Film Coating Machine Model: N/A Standard: N/A Issued by: UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co. Issue Date: 25 Jan., 2021 Certificate Name: CE NO.: M.2020.206.C61803 Product Name: Automatic Cartoning Machine Model: N/A Standard: N/A Issued by: UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co. Issue Date: 18 Mar., 2021 <input type="checkbox"/> UL <input type="checkbox"/> CCC <input type="checkbox"/> RoHS <input type="checkbox"/> FCC <input type="checkbox"/> Others <input type="checkbox"/> NIL

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Test reports for raw materials	<input type="checkbox"/> RoHS <input type="checkbox"/> Reach <input type="checkbox"/> Others <input checked="" type="checkbox"/> NIL
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Part E: Production Capacity & Quality Control

Remark: The audit content of this part relates only to its associated enterprise (Wenzhou Mintech Machinery Technology Co.,Ltd)

Section 1: Production Capacity

1.1 Production Workflow Chart					
	→		→		→
Cutting		Welding		Assembling	
	→				
Test		Packing			
1.2 Products Situation (Top three Product Categories)					
Product	Price range	Min. order quantity	Top monthly output	Average monthly output	Total in 2020
 Pharmaceutical Machinery	Confidential	Confidential	Confidential	Confidential	Confidential
1.3 Main Facilities					
Picture	Facility name	Brand or Country/Region of origin	Target Value/machine*day	Quantity	
	Bench Drill	China	Confidential	1	
	Cutting Facility	China	Confidential	1	

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	Grinding Facility	China	Confidential	1
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Section 2: Production Process Control

2.1 Production Process Control		
Item	Content	Observations /Comments
1	Product R&D capacity	<input checked="" type="checkbox"/> Own brand <input checked="" type="checkbox"/> ODM <input checked="" type="checkbox"/> OEM
2	Are the environmental conditions, such as tidiness and cleanliness being controlled and suitable for the operation performed?	<input type="checkbox"/> Very tidy <input checked="" type="checkbox"/> Normal <input type="checkbox"/> Need to improve <input type="checkbox"/> Very poor
3	Are the necessary items /documents provided at appropriate location and under control?	<input checked="" type="checkbox"/> Work Instructions /procedures <input type="checkbox"/> Workmanship standard /acceptance <input type="checkbox"/> Golden sample /Approval sample <input type="checkbox"/> Product picture <input type="checkbox"/> Verbal by workshop director
4	Are written instructions available for incoming material inspections /testing? Is the relevant record maintained?	<input type="checkbox"/> Has instructions and uniformly followed <input type="checkbox"/> Has instruction but no written records <input checked="" type="checkbox"/> Materials checked by storage staff
5	Are written inspections /testing instructions available for finished products? Is the relevant record maintained?	<input checked="" type="checkbox"/> Have instructions and uniformly followed <input type="checkbox"/> Have instruction but no written records <input type="checkbox"/> Finished product checked by packing staff
6	What type of inspection is used for finished products?	<input type="checkbox"/> Random inspection <input type="checkbox"/> Visual inspection <input type="checkbox"/> Function inspection <input checked="" type="checkbox"/> 100% inspection <input checked="" type="checkbox"/> Visual inspection <input checked="" type="checkbox"/> Function inspection
7	Are non-conforming units clearly marked/ segregated to prevent accidental dispatch?	<input type="checkbox"/> Marked and segregated <input type="checkbox"/> Segregated but not marked clearly <input checked="" type="checkbox"/> Not found on site
8	How are the non-conforming units handled?	<input checked="" type="checkbox"/> Repaired and re-inspection <input type="checkbox"/> Picked out <input type="checkbox"/> Used under control <input type="checkbox"/> Others

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Part G: Working Environment

Section 1: Working Environment

1.1 Welfare Benefits		
Item	Content	Observations /Comments
1	Does the company have effective procedures to verify the age of staff at the time of recruitment?	<input checked="" type="checkbox"/> Has written procedure and keeps adequate age documents of workers <input type="checkbox"/> Has written procedure but doesn't follow records <input type="checkbox"/> Hasn't written procedure or follows records
2	Do all workers sign employment contracts with the factory?	<input checked="" type="checkbox"/> All workers sign employment contracts <input type="checkbox"/> Some workers sign employment contracts <input type="checkbox"/> Only management staff sign employment contracts <input type="checkbox"/> No staff sign employment contracts
3	Is statutory contribution required for all employees' social insurance (e.g. health insurance, unemployment insurance, accident insurance etc.) paid for by the enterprise?	<input checked="" type="checkbox"/> All workers have social insurance. <input type="checkbox"/> Some workers have social insurance <input type="checkbox"/> Only management staffs have social insurance <input type="checkbox"/> No staff have social insurance
4	Does the company have a clear and effective policy on working hours, rest and vacations? If does, please list it.	<input checked="" type="checkbox"/> All staffs work kept to the policy <input type="checkbox"/> Most of the time it keeps to the policy except midseason. <input type="checkbox"/> Usually needs overtime. <input type="checkbox"/> No relevant records for working hours Describe the working hours: From Monday to Friday; 08:30-11:30, 13:00-17:00
5	Does the company pay extra remunerations for all overtime work?	<input checked="" type="checkbox"/> For all overtime work. <input type="checkbox"/> For official holidays <input type="checkbox"/> For official holidays except weekend. <input type="checkbox"/> No extra remunerations for overtime.
6	Does the company have dormitories for staff? If yes, please describe the condition.	<input type="checkbox"/> Provide dormitories for all staff <input type="checkbox"/> Provide dormitories for workers <input type="checkbox"/> Provide dormitories for management staff <input checked="" type="checkbox"/> No dormitories were provided. Describe the condition: N/A
1.2 Labor Protection		
Item	Content	Observations /Comments
1	Are there uniforms for all staff in company?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Other
2	Is the emergency medical supplies enough and easily used in workshop?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Other
3	Does the company arrange health and safety training for new workers?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Other
4	Do the workers have the appropriate protective equipment during operation in workshop? Such as gloves, masks.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Other
5	Is there training needed and carried out for fire protection?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Other

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Part H: Energy Saving and Emission Reduction

Section 1: Environmental Management

1.1 Environmental Management		
Item	Content	Observations /Comments
1	Environmental Management System	<input type="checkbox"/> ISO 14001 Certificate <input type="checkbox"/> Cleaner production management <input checked="" type="checkbox"/> NIL
2	Environmental Impact Assessment	<input type="checkbox"/> The Report of Environmental impact assessment is approved by EPA . <input checked="" type="checkbox"/> NIL
3	Check and Acceptance of Completed Constructive Projects	<input type="checkbox"/> The Report Completed Constructive Projects Inspection and Acceptance is approved. <input checked="" type="checkbox"/> NIL
4	"Three Simultaneity" for Environmental protection	<input type="checkbox"/> The Report of "Three Simultaneity" for Environmental protection Inspection and Acceptance is available. <input checked="" type="checkbox"/> NIL

Section 2: Water, Gas and Noise Control

2.1 Water, Gas and Noise Control		
Item	Content	Observations /Comments
1	Water-intaking	<input type="checkbox"/> Water-intaking license <input type="checkbox"/> No water-intaking license <input checked="" type="checkbox"/> No water taken from natural water body
2	Waste water	<input type="checkbox"/> Water-draining license or contract <input type="checkbox"/> Having carried out waste water treatment before draining <input type="checkbox"/> Having carried out waste water monitoring and the result of which being within the standard limit <input checked="" type="checkbox"/> No detail activities were found
3	Emission to air	<input type="checkbox"/> Air pollutant emission license <input type="checkbox"/> Having carried out air pollutant emission monitoring and the result of which being within the standard limit <input checked="" type="checkbox"/> No detail activities were found to reduce emission to air
4	Classification and Recycling for solid waste	<input type="checkbox"/> Having applied trash classification recycling <input checked="" type="checkbox"/> Having special warehouse for hazardous waste <input type="checkbox"/> No detail activities were found
5	Noise	<input type="checkbox"/> The company carried out noise monitoring and the result of which being within the standard limit one time per year <input checked="" type="checkbox"/> No detail activities were found



Part J: Photos

Section 1: Photos of Documents

1.1 Photos of Documents

Description: Business License



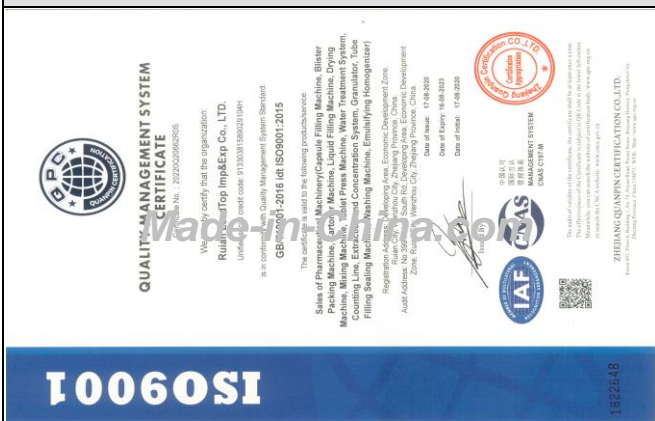
Description: Business License (associated company)



Description: Export License



Description: ISO90012015 Certificate



Description: CE



Description: CE



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Description: CE

		<h1 style="text-align: center;">CERTIFICATE</h1>	
<h2 style="text-align: center;">ATTESTATION CERTIFICATE OF MACHINERY AND ELECTROMAGNETIC COMPATIBILITY DIRECTIVES</h2>			
<p>Technical file of the company mentioned below has been observed</p> <p>2004/42/EC Machinery Directive and 2004/108/EC Electromagnetic Compatibility Directive</p> <p>Company Name : Chengdu Jialu Electronic Technology Co., Ltd.</p> <p>Address : Room 1001, No. 100, Jialu Road, Chengdu, Sichuan, China</p> <p>Company Address : Chengdu Jialu Electronic Development Zone, Ruan City, Wenzhou City, Zhejiang, China</p> <p>Manufacturer Name : Cheng JTPM Group Co., Limited</p> <p>Manufacturer Address : 2004/42/EC Machinery Directive</p> <p>Related Directives and Annex : 2004/108/EC Electromagnetic Compatibility</p> <p>Related Standards : EN IEC 11090-1, EN IEC 11090-2, EN IEC 11090-3, EN IEC 11090-4, EN IEC 11090-5, EN IEC 11090-6, EN IEC 11090-7, EN IEC 11090-8, EN IEC 11090-9, EN IEC 11090-10, EN IEC 11090-11, EN IEC 11090-12, EN IEC 11090-13, EN IEC 11090-14, EN IEC 11090-15, EN IEC 11090-16, EN IEC 11090-17, EN IEC 11090-18, EN IEC 11090-19, EN IEC 11090-20, EN IEC 11090-21, EN IEC 11090-22, 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Section 2: Photos of Company

2.1 Photos of Company and Product Sample

<p>Description: Company Gate</p> 	<p>Description: Company Gate (associated company)</p> 
<p>Description: Office</p> 	<p>Description: Office</p> 
<p>Description: Workshop</p> 	<p>Description: Workshop</p> 

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Description: Product Sample



Description: Product Sample



Description: Product Sample



Description: Product Sample



-- End of the Report --

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