



Audit Report

Report NO.: QIP-ASI2551979

Audit Date: 2025-12-22

Holder:**Company Name (English):** Shandong Zhongke Medical Equipment Co., Ltd.**Company Name (Chinese):** 山东中科医疗器械有限公司**Showroom:** <https://zkmedical.en.made-in-china.com>**Registered address:** No. 588, Qihe Village, Zhonglou Town, Lanshan District, Rizhao City, Shangdong Province, China**Actual address:** No. 588, Qihe Village, Zhonglou Town, Lanshan District, Rizhao City, Shangdong Province, China**Indent Type:** • Initial Audit**Main Product:** Prefilled Syringe

Sign for and on behalf of SGS-CSTC Standards Technical Services Co., Ltd.

Auditor: Tek Tao**Reviewed by:** Ellie Jin

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1. General Information

1.1 Company Overview

Company Name (Chinese): 山东中科医疗器械有限公司

Company Name (English): Shandong Zhongke Medical Equipment Co., Ltd.

Is the English name an offshore company name? ☐ Yes ☒ No

Showroom: <https://zkmedical.en.made-in-china.com>

Audited site: No. 588, Qihe Village, Zhonglou Town, Lanshan District, Rizhao City, Shangdong Province, China

Product: Prefilled Syringe

General Comments: Shandong Zhongke Medical Equipment Co., Ltd. is a manufacturer and trading company; it was established in 2015, located in No. 588, Qihe Village, Zhonglou Town, Lanshan District, Rizhao City, Shangdong Province, China. The workshops occupy an area of more than 1300 square meters. The company has passed ISO9001 and ISO13485 certification in 2023.

Indent Type: • Initial

Company Photos:



Contents:

- 1. General Information
- 2. Export Trade Capacity
- 3. Manufacturing Capacity
- 4. Service Capacity
- 5. Quality Control Capacity
- 6. R&D Capacity
- 7. Financial Capacity
- 8. Sustainable Development Capacity
- 9. Photos

1.2 Company Information



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Registration Number : 91371103MA3T81U146

Name of legal representative : Ms. Mei Zhang

Year of established : 2020-06-08

Valid Date : Long term

Registered capital : 6180000 CNY

Company Area : 1300 square meters

Registered address :

No. 588, Qihe Village, Zhonglou Town, Lanshan District, Rizhao City, Shangdong Province, China

Business scope :

General projects: Production of Class I medical devices; Sale of Class I medical devices; Sale of rubber products; Manufacturing of plastic products; Sale of molds; Manufacturing of molds; Sale of plastic products; Sale of Class II medical devices; Manufacturing of rubber products; Technical services, technology development, technical consultation, technical exchange, technology transfer, technology promotion; Manufacturing of medical packaging materials; Manufacturing of daily glass products; Packaging services; Manufacturing of technical glass products; Wholesale of medical staff protection supplies; Production of medical staff protection supplies (Class I medical devices); Sale of food (only sale of pre-packaged food); Internet sale of food (only sale of pre-packaged food); Internet sales (except for goods that require licensing); Import and export of goods; Engineering and technical research and experimental development; Sales of hygiene products and disposable medical supplies; Manufacturing of metal packaging containers and materials; Sale of technical glass products; Manufacturing of hardware products; Research and development of hardware products; Retail of hardware products; Sale of packaging materials and products; Sale of daily necessities; Sale of packaging-specific equipment; Sale of daily glass products; Health consultation services (excluding medical treatment services); Retail of medical staff protection supplies; Sale of food plastic packaging container tools products. (Except for projects that require approval, operate independently based on the business license.) Permitted projects: Operation of Class III medical devices; Medical services; Production of Class II medical devices; Production of medical staff protection supplies (Class II medical devices); Medical device internet information services; Production of Class III medical devices; Manufacturing of food plastic packaging container tools products. (Projects that require approval must be carried out after obtaining the relevant approval from the relevant departments. The specific business items are subject to the approval documents or licenses issued by the relevant departments.)

Products

manufactured /sold scope : Prefilled Syringe

Type of ownership :

- Limited Company

Company type :

- Combined

Associated company :

☐ Yes ☒ No

1.3 Employees Details

Explanation of code and employee details :



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Code	Department	Number of employees
A	GM	1
B	Admin. Dept.	1
C	Sales Dept.	4
D	Technical Dept.	5
E	Quality Control Dept.	15
F	Production Dept.	14
Number in total : 40		

1.4 Contact Information

Contact person : Ms. Tina
 Phone number : 19213061376
 URL/Web address : <https://zkmedical.en.made-in-china.com>



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2. Export Trade Capacity

Export Trade Capacity

Does the company have a valid Import and Export license? ☒ Yes ☐ No

Customers Quantity : Confidential

Export experience : 6 Years

Proportion of foreign trade market : • 50%~80%

Repeat Buyers Choice : • 50%~80%

Cooperated with Fortune 500 : ☐ Yes ☒ No

The language freely used by foreign trade staff : • English

The number of foreign trading staff with relevant trading experience :

• 1-5 years 2 staff

Total staffs : 2

Main Export Market :

Market	Main Product	Main client
Domestic Market	Prefilled Syringe	Confidential



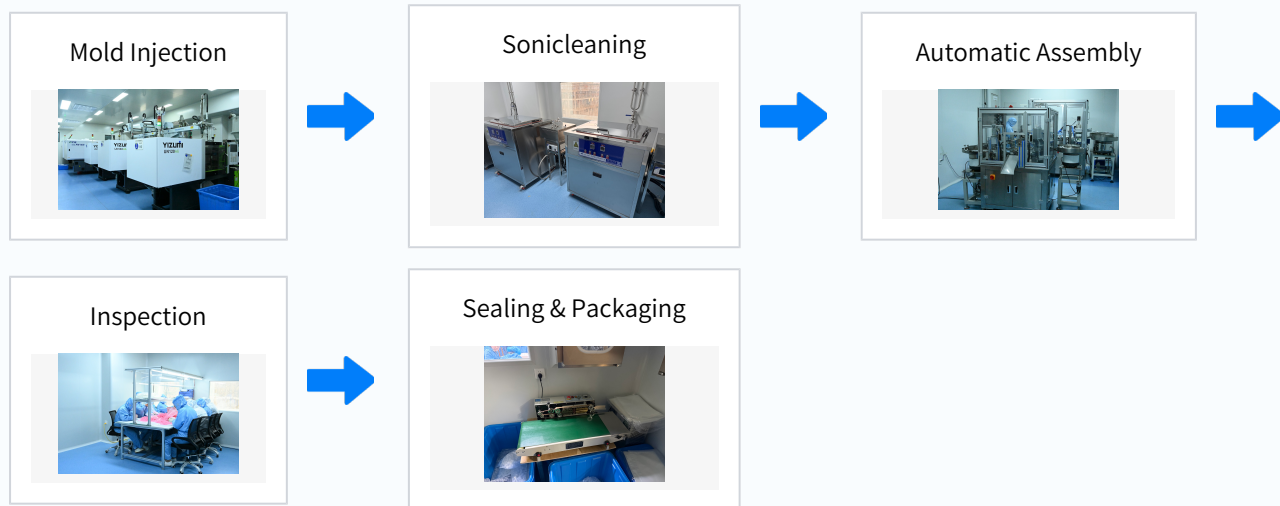
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3. Manufacturing Capacity

Manufacturing Capacity

Number of production lines : 1

Production Workflow Chart :



Products Situation (Top five Product Categories) :

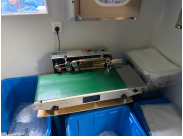
Product	Price range	Min. order quantity	Top monthly output	Average monthly output	Total in Last Year
	Confidential	1000 Pieces	Confidential	6000000 Pieces	Confidential

Main Facilities :

Picture	Facility name	Brand of Country/ Region of origin	Target Value/ machine*day	Quantity
	Mold Injection Machine	Confidential	Confidential	10
	Sonicleaning Machine	Confidential	Confidential	4



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	Automatic Assembly Machine	Confidential	Confidential	3
	Packaging Machine	Confidential	Confidential	1

Does the factory conduct an ongoing volume reconciliation per lot or batch production to balance the quantities of claimed material purchased, in stock, and sold? ☐ Yes ☒ No

If outsource process was proceeded, does the factory establish outsource SOP? ☒ Yes ☐ No

Does the factory have a valid contract with each associated sub-contractor? ☐ Yes ☒ No



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4. Service Capacity

4.1 Overseas service capacity

- Do you have In-stock capacity? ☒ Yes ☐ No
- Do you have an overseas warehouse? ☐ Yes ☒ No
- Do you have an overseas showroom? ☐ Yes ☒ No
- Do you have an overseas agent/branch? ☐ Yes ☒ No
- Minimum order quantity : 1000 Pieces
- Have you participated in offline trade shows? ☐ Yes ☒ No

4.2 Export Overall Situation

- Overseas services countries : ☐ Yes ☒ No
- The content of overseas services provided : • N/A
- Nearest port : Qingdao Port
- Acceptable quotation terms : • FOB
• CIF
• CFR
• EXW
- Acceptable payment terms : • LC • T/T
- Average lead time (Peak Season) : • within 15 workdays
- Average lead time (Off Season) : • within 15 workdays

4.3 Supplier Management

- Number of qualified suppliers : 10
- Does the company establish and implement an effective suppliers' assessment procedure?
- Have the written procedures and followed records
- Does the company have an updated list of approved suppliers?
- Provided some suppliers names



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Are corrective & preventive actions mechanism established and implemented effectively (including the suppliers / sub-contractors control, incoming inspection, process control, final inspection and customer complaint)?

- Has the clear procedure and followed records

Is there a clear procedure for handling customer complaints?

- Has the clear procedure and followed records



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5. Quality Control Capacity

5.1 Overall situation

Is there quality assurance? ☒ Yes ☐ No

5.2 Quality Management

Is there traceability identification of raw materials? ☒ Yes ☐ No

Are written instructions available for onsite material inspection/testing? Are the relevant records maintained?

- Has instructions and uniformly followed

Are the necessary items /documents provided at appropriate location and under control?

- Work Instructions /procedures

Are written inspections /testing instructions available for finished products and the relevant record maintained?

- Have instructions and uniformly followed

What type of inspection is used for finished products?

- 100% inspection: • Visual inspection

Are non-conforming units clearly marked/ segregated to prevent accidental dispatch?

- Marked and segregated

How are the non-conforming units handled?

- Picked out

Is there warehouse control process and records?

- With written procedure and kept relevant records

Number of QA and QC inspection staffs : 15

Test Equipment Situation :

Equipment name	Model	Quantity	Useful life
N/A	N/A	N/A	N/A



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6. R&D Capacity

R&D Capacity

There is/are 5 R&D engineer(s) in the company.

What is the main job responsibility for R&D engineers?

R&D new product, design drawing with software, provided technology support during production; make product specification for client approved.

Is there any relevant design input, output, review, verification, and validation documentation available for auditor to review ?

☒ Yes ☐ No

What are the software and instruments that R&D employees are using?

Auto CAD, Photoshop

Patent Situation :

Patent name	Quantity	Patents Awarded
Two-color pre-filled syringe	1	Design Patent Certificate
Pre-filled syringe (1ml COP set)	1	Design Patent Certificate
Thrust rod of the booster	1	Design Patent Certificate
Ruel joint assembly	1	Design Patent Certificate

Trademark Information : Yomary

Trademark Quantity in total : 1

Do you have private mold? ☒ Yes ☐ No

Is it professional technique supplier? ☒ Yes ☐ No

Do you provide 3D software design services? ☒ Yes ☐ No

What design services are provided?

- Customization from Samples
- Customization from Designs
- Full Customization
- Minor Customization
- Flexible customization

Are there any new products in the past year ? ☐ Yes ☒ No

ODM service available : ☒ Yes ☐ No

OEM for popular brands ☒ Yes ☐ No

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Is there SDK available? ☐ Yes ☒ No



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7. Financial Capacity

Financial Capacity

Financial Data :

Item	Content	2024	2023	2022
1	Operating revenue	Confidential	Confidential	Confidential
2	Operating cost	Confidential	Confidential	Confidential
3	Gross profit	Confidential	Confidential	Confidential
4	Operating profit	Confidential	Confidential	Confidential

Balance Sheet :

Item	Content	2024	2023	2022
1	Cash and cash equivalents	Confidential	Confidential	Confidential
2	Total current assets	Confidential	Confidential	Confidential
3	Total current liabilities	Confidential	Confidential	Confidential
4	Total assets	Confidential	Confidential	Confidential

Cash Flow from Operating Activities :

Item	Content	2024	2023	2022
1	Cash received from sales of goods or rendering of services	Confidential	Confidential	Confidential
2	Sub-total of cash inflows	Confidential	Confidential	Confidential
3	Sub-total of cash outflows	Confidential	Confidential	Confidential

Key Performance Indication :

Item	Content	2024	2023	2022
1	Operating revenues year-on-year rise: (OR in this year- OR in last year) / (OR in last year)	Confidential	Confidential	Confidential



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2	Gross Margin: Gross profit/ Operating revenues	Confidential	Confidential	Confidential
3	Current ratio: Current assets / Current liabilities	Confidential	Confidential	Confidential

Remark: Confidential



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8. Sustainable Development Capacity

8.1 Certification and Report

Management system certification :

- ISO9001:2015 certificate
- ISO13485:2016

Does the company hold regular fire drills in last year ? ☒ Yes ☐ No

8.2 Environment management

Does the company have factory environmental impact assessment report ? ☐ Yes ☒ No

Does the company have EIA reply ? ☐ Yes ☒ No

Is the actual founding consistent with EIA acceptance comments ? ☐ Yes ☒ No

Does the company have Pollution discharge permit ? ☐ Yes ☒ No

Does the company have Fixed pollution source pollution discharge registration ? ☐ Yes ☒ No

8.3 Enterprise digital transformation

Business digitization :

Has the enterprise started the construction of enterprise digitalization process at this stage? ☐ Yes ☒ No

Has the enterprise established a technical transformation plan? ☐ Yes ☒ No

Does the enterprise currently establish a database based on digital construction to effectively collect and monitor big data in real time? ☐ Yes ☒ No

Management digitization :

Does the enterprise establish and use ERP system to realize digital management of production, procurement, quality control, logistics and other processes? ☐ Yes ☒ No

Does the enterprise establish and use OA system to manage all processes? ☐ Yes ☒ No

Has the enterprise established a CRM system for customer relationship management? ☐ Yes ☒ No

Operation digitization :

Has the enterprise established SAP system for the management of internal financial system? ☐ Yes ☒ No

Has the enterprise established an AI model to process big data and achieve decision enabling management? ☐ Yes ☒ No



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9. Photos

9.1 Photos of Documents

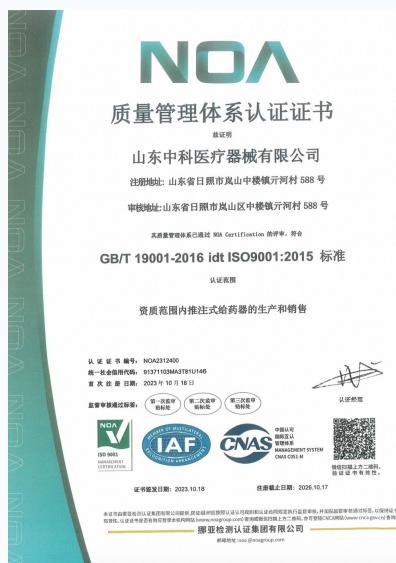
Business License



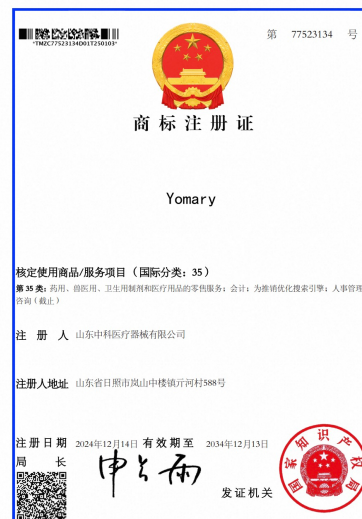
ISO13458 Certificate



ISO9001 Certificate



Trademark



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Patent Certificate



Patent Certificate



Patent Certificate



Patent Certificate



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9.2 Photos of Company and Product Sample

Workshop Gate



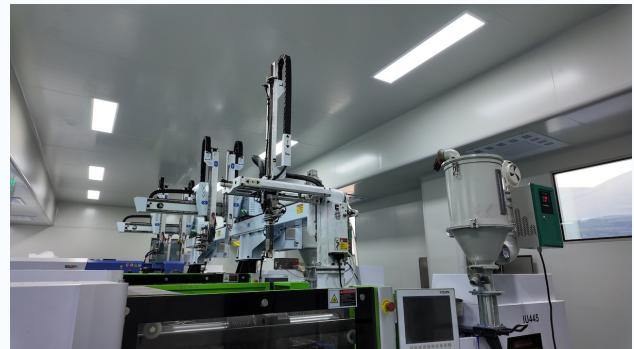
Air Shower



Workshop



Workshop



Workshop



Workshop



Product Sample



Product Sample



Product Sample



Product Sample



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Product Sample



Product Sample



Product Sample



Product Sample



Product Sample



Product Sample





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