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# Diagnosing China's Healthcare industry

Riccardo Benussi  
International Business Advisory Senior Associate  
Dezan Shira & Associates – Shanghai Office  
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Defining  
the scope

Diagnosing

Focus



# Contents

Limited space and time to discuss, so . . .

Healthcare

Elderly care

Medical devices

Opportunities

Intellectual Property

Are you geared up?



# Background

- As many countries, China has experienced great dissatisfaction with the healthcare system:
  - due to underfunding,
  - urban and rural inequalities,
  - and overpriced, low-quality products and services.
- On top of this: pollution, low quality food, counterfeit medicines and cosmetics and less than modern medical appliances have raised concerns at all social and government levels.
- However, and since the launch of the 2009 health reforms, China has substantially increased investment to expand health infrastructure; strengthened the primary-care system; achieved near-universal health insurance coverage in a relatively short period; continued to promote equal access to basic public health services; deepened public hospital reform; and improved the availability, equity and affordability of health services. It has also greatly reduced child and maternal mortality and rates of infectious diseases, and improved the health and life expectancy.

# Healthcare reforms in China

2003

- SARS outbreak triggers reforms

2007

- State Council lays out draft for targets in 2020

2009

- Healthcare reform – phase 1 → better insurance coverage and infrastructure

2012

- Healthcare reform – phase 2 → expansion to rest of the Country; more infrastructure

2016 (2017-2020)

- Healthcare reform – phase 3 → implementation will reflect outcomes of phase 2

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# Current stage

We are seeing massive ongoing government spending, increase of infrastructure, more specialized personnel and more health-oriented “culture of health”.

The country’s increasing population is a louder wake up call on how the elderly and children need to be assisted by infrastructure, a labor force of qualified staff, and ever more modern appliances, and devices. And all this, efficient and affordable!

Local production has largely lost trust of most of domestic consumers, and while these companies are slowly but surely regaining shares of the market, consumers naturally turn to imported goods and foreign services locally available, and are willing to pay premiums all along, to acquire “first world well being”.

# Current stage

## Policy

Health care issues will be one of the top drivers of the Chinese economy for the next decade.

## Spending

The country's annual expenditure is projected to grow at an average rate of 11.8 % per year in 2014-2018, reaching \$892 billion by 2018

## Opportunities:

e.g. from pharma to vegetarian restaurants, from prosthetics to healthy snacks, the trend is growing and is here to stay.

# Elderly care - an encouraged sector

## Sector analysis

- Origins of such need:
  - Urbanization
  - More sophisticated types of demand
  - Aging population → people over 60 are 222 Mio (16% of PRC's population)
    - Figure is predicted to grow by 3% year on year
    - More individuals are willing to live in elderly care homes
  - Private sector could support the demand public infrastructure cannot meet
  - Sector will be worth more than real estate by 2020.
- Private hospitals and specialty divisions
- Nursing homes and children hospitals
- Insurance and premium healthcare



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# Opening up the sector: legal evolution

- In September **2013**, the State Council released the “Opinions on Accelerating the Development of the Elderly Care Industry and Pension System (Guo Fa [2013] No.35),” which contains the general policy on encouraging foreign investment in the elderly care industry.
- In **2014**, the Ministry of Commerce (MOC) and Ministry of Civil Affairs (MCA) jointly issued “Circular on Various Issues on Foreign Investment in For-Profit Senior Care Institution” (MOC and MCA Announcement [2014] No.81, “Circular 81”), which states that **foreign investors are encouraged to set up either wholly foreign-owned for-profit elderly care institutions or joint ventures with Chinese partners.** Additionally, foreign investors are permitted to make related investments in elderly care in China, which allows them to establish large-scale, chained operations.
- The “Catalog of Industries for Guiding Foreign Investment”, released by the Ministry of Commerce in **2015**, shows that FDI into **elderly care is classified as encouraged.** This affords foreign investors the same status as Chinese domestic investors.

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# Stages of a setup and requirements (1/2)

among other documentation. . .

- **1. Obtain “foreign investment” approval, by. . .**
  - Business scope
  - Articles of Association
  - Company Name
  - Proving working experience in the elderly care sector.
- **2. Register with the Administration for Industry and Commerce (AIC)**
  - Shareholder’s information
  - Appointment of the legal representative
  - Lease agreement

# Stages of a setup and requirements (2/2)

among other documentation. . .

- **3. Apply for “elderly care institution establishment” permit**
  - Meet environmental protection requirements and other technical standards
  - Have professional and technical personnel
  - Have over (##) beds
  - Have enough working capital to sustain operations
- **4. Additional procedures for providing healthcare services**
  - Apply for approval and operation registration. The process involved is significantly more efficient than the general medical institution application.
- ***Preferential tax policies and other incentives***
  - VAT exemptions
  - Reduced admin fees
  - Favorable utility prices

# Medical devices



# Government bodies and legal framework

- Medical devices
  - WHO's definition: *An article, instrument, apparatus or machine that is used in the prevention, diagnosis or treatment of illness or disease, or for detecting, measuring, restoring, correcting or modifying the structure or function of the body for some health purpose.* \* (As defined by the WHO Global Harmonization Task Force in May 2012)
  - Regulatory players, among others:
    - Ministry of Health (MOH) [www.moh.gov.cn](http://www.moh.gov.cn) and
    - China State Food and Drug Administration (CFDA) [www.sfda.gov.cn](http://www.sfda.gov.cn)

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# Medical device industry - highlights

- China relies heavily on **foreign imports** for its medical supplies and devices.
  - Especially true for high-tech, high-price items, for which the U.S., Germany and Japan serve as major exporters.
- Additionally, there are several thousand **local** manufacturers of medical devices - mostly small companies with low revenues - roughly 90 percent of whom are makers of low quality goods.
- The majority of **high-tech equipment is imported**; e.g., 80 percent of scanners, 90 percent of ultrasound equipment and 90 percent of MRI equipment is manufactured abroad. Imports of mid-to-high end products have decreased recently, *but this has largely been due to foreign companies moving their production plants to China.*

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# Medical device industry – legal framework

## Supervisory and administrative authorities for the medical device industry

- **At national level**, the China Food and Drug Administration (“CFDA”), is in charge of the regulation and control of the medical device industry for country.
- In practice, the **CFDA delegates** to its local branches in provinces, autonomous regions and directly-controlled municipalities.
- These bodies issue **specific licenses** and product registration certificates to medical device companies at provincial level.
- *However, local FDAs may have more detailed and specific examination and approval requirements than those of the CFDA. Consequently, when investing in the medical device industry, both **national and local requirements** must be met.*



# Medical device industry – legal framework

## Risk-based classification and administration

- Basically, medical device classification in China is determined according to *CFDA Order No. 15* and other CFDA documents. While there are many factors related to classification, devices are essentially divided into three classes based on the risk they present to patients or users.
- **Class I Medical Devices** are those with **low risk degree** and for which safety and effectiveness can be ensured through routine administration.
- **Class II Medical Devices** are those with **moderate risk** and for which strict administration is required to ensure their safety and effectiveness
- **Class III Medical Devices** are those with **higher risk** and for which must be strictly controlled via special measures in respect to safety and effectiveness
- The classification regime for medical devices differs from those in the European Union and United States. For example, a device considered Class II in the U.S. or Class II-a / II-b in the E.U. may be considered Class III in China, meaning its registration process will be longer and more costly.

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# Medical device industry – legal framework

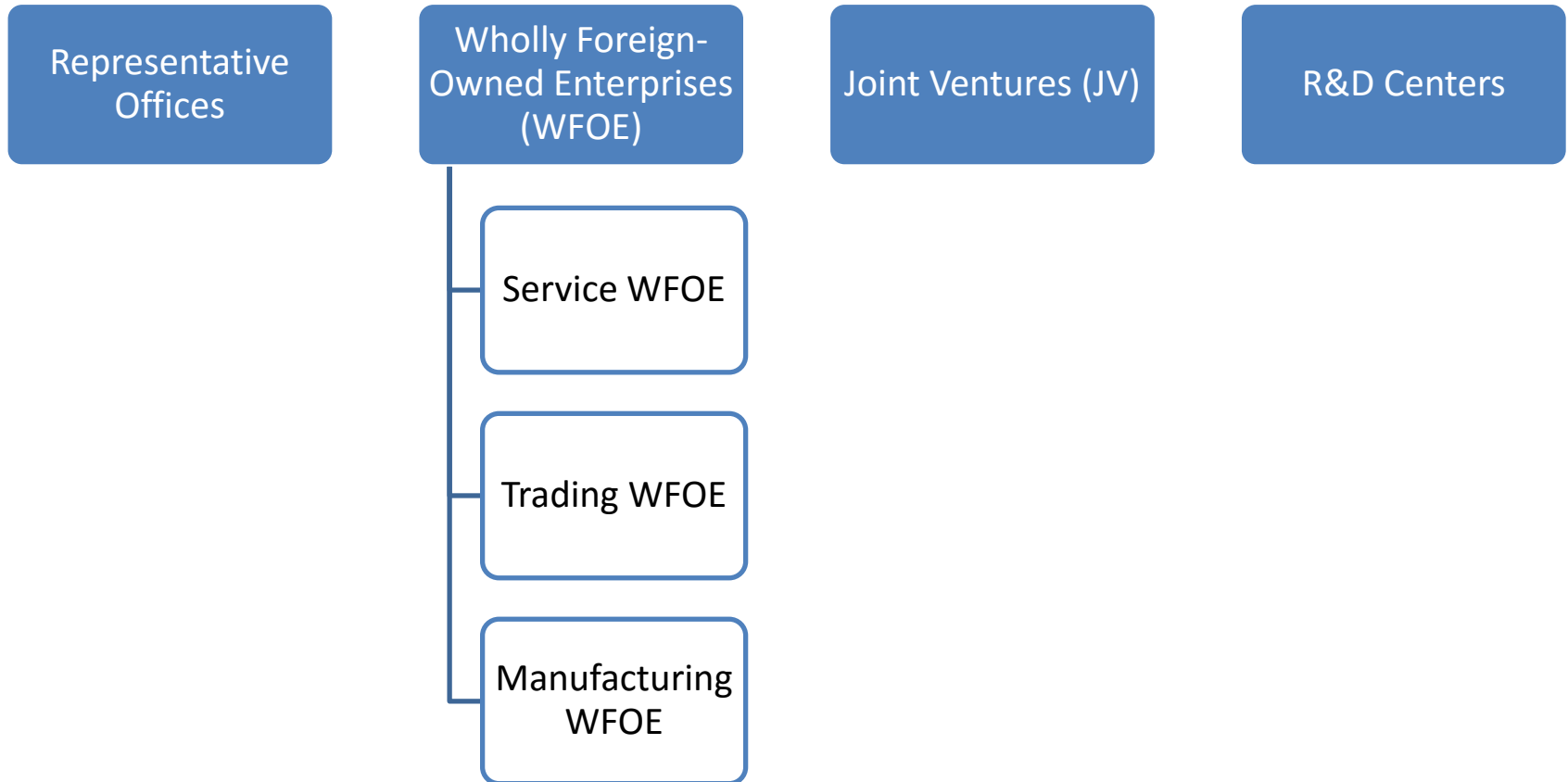
## Licensing regime

- Generally, any commercial entity engaged in the manufacture or trade of medical devices must obtain **specific licenses** in addition to the standard business licenses for operating a company in China.
- The procedures and requirements vary significantly depending on the classification
- The devices themselves will need to be registered with the relevant authorities. Based on the amended *State Council Order No. 650*, applicants are no longer required to obtain a medical device manufacturing license before being able to register the devices themselves, provided they are fully in compliance with good manufacturing practices during product design and development.
- This allows the few foreign R&D centers to apply for product registration without first finishing construction of their manufacturing facilities, saving them a substantial amount of time and resources.

# Foreign direct investment's role



# Corporate establishment



# Investment vehicles

	Manufacturing WFOE	Trading WFOE (FICE)
Requirements	<ul style="list-style-type: none"> <li>• Production <b>premises</b>, environmental <b>conditions</b>, production <b>equipment</b> and professional <b>technicians</b> suitable for the production of medical devices;</li> <li>• A staff of full-time <b>product testers</b> and testing equipment to test quality of the medical devices produced;</li> <li>• A management system to <b>ensure quality</b> of the medical devices;</li> <li>• An <b>after-sale service</b> capacity in line with the medical devices produced; and</li> <li>• Other requirements as stated in the documents on product development and production process.</li> </ul>	<ul style="list-style-type: none"> <li>• A suitable <b>quality management mechanism</b> or personnel with relevant professional credentials or titles recognized by the State;</li> <li>• <b>Suitable business and storage premises</b> in relation to the enterprise's business scope and scale of operations;</li> <li>• Professional guidance, technical training and after-sale services capabilities or an agreement to receive technical support from relevant agencies.</li> </ul> <p>Note: For Class-III traders, a digital management system is required to ensure the traceability of medical devices.</p>
Licenses	<p>Class I: Record-filing Class II/III: Medical device manufacturing license</p> <p>Note: Approved medical device manufacturers may distribute their self-produced and previously licensed devices without applying for a trading license.</p>	<p>Class I: No requirements Class II: Record-filing Class III: Medical device trading license</p>
SETUP TIME	8 to 12 months or more	5 to 6 months

# Wholly Foreign Owned Enterprises (WFOE)

## Establishing a Medical Device Manufacturing/Trading Company

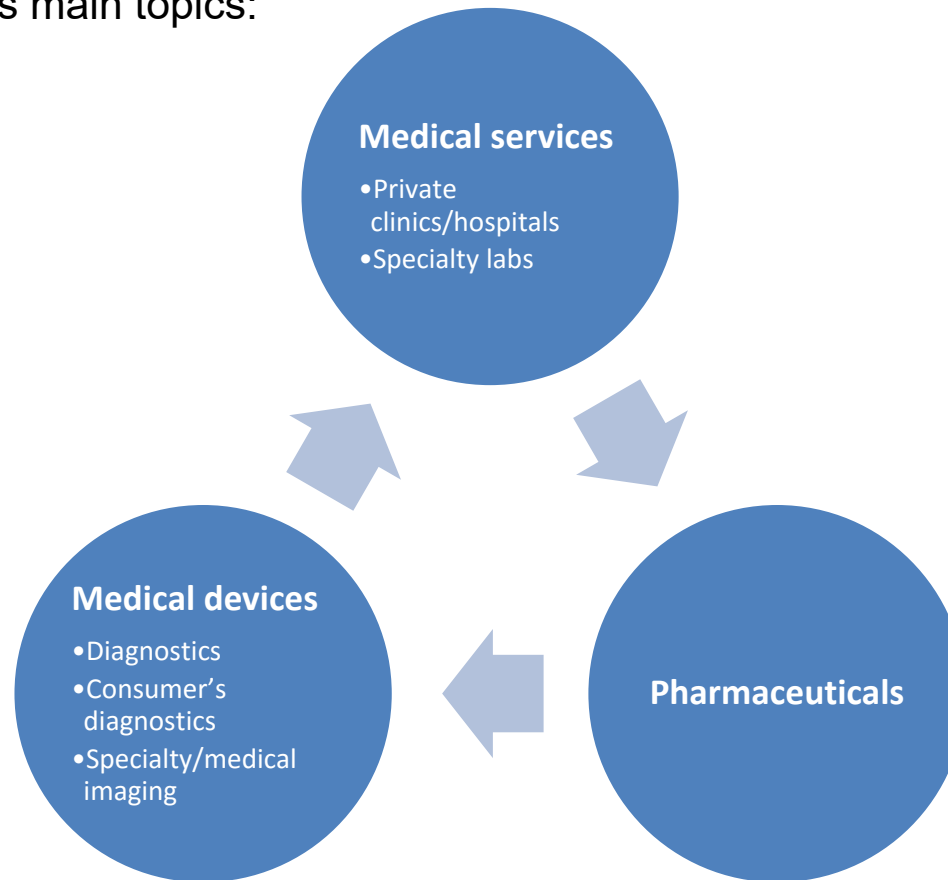


# Opportunities



# Opportunities – for services and devices (1/2)

In relation to today's main topics:





# Opportunities – for services and devices (2/2)

- **Most of Chinese healthcare institutions and related services lack in:**
  - «Western style» patient satisfaction/experience
  - IT systems
  - Marketing
- **Defining the scope and other investment areas:**
  - Healthy and functional food
  - Indoor air purifiers and relevant gear
  - Gyms and technical apparel
  - Cosmetic surgery
  - Outbound treatment: «medical tourism»
  - **«Mobile healthcare»**
    - Telemedicine
    - Improved on-line prescription sales (remote treatment)
    - Wearable technology
    - Integrated services
    - TCM and Western

# Opportunities

- While China's healthcare reform is in phase 3, a combination of . . .
  - Telemedicine
  - National medical records platform
  - Specialty physician diagnosis
  - On-line prescription sales
  - Integrated on-line scheduling and follow-up diagnosis

. . . could result in extremely interesting shores in the sector because these sectors are either encouraged or straightforward to access.

In any case, a major **reality check is needed** if your business plan seriously includes joining this high-paced environment, its competition, and regulations → →

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# “Before-you-go” checklist for the investor

- **Branding**
  - Be better at marketing your experience and technical leading edge
  - Build brand awareness
- **Enterprise setup or acquisition:**
  - For 100% ownership
    - Of specialized staff
    - Of entire hospitals privately held
  - Joint ventures with R&D centers or distributors
- **Target a niche or know your competition**
  - Create more value with a business model where competition is still low: invest in customized market access reports to know before you go. [Asia Briefing](#)
- **Can you diversify and maintain competitive pricing?**

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# Final remarks on hurdles

- Lack of clarity in regulations and competencies at government level
- Market entry costs
- Protectionism
- Reliability of business partners
- Human Resources

# Intellectual Property concerns

Proactively protect your

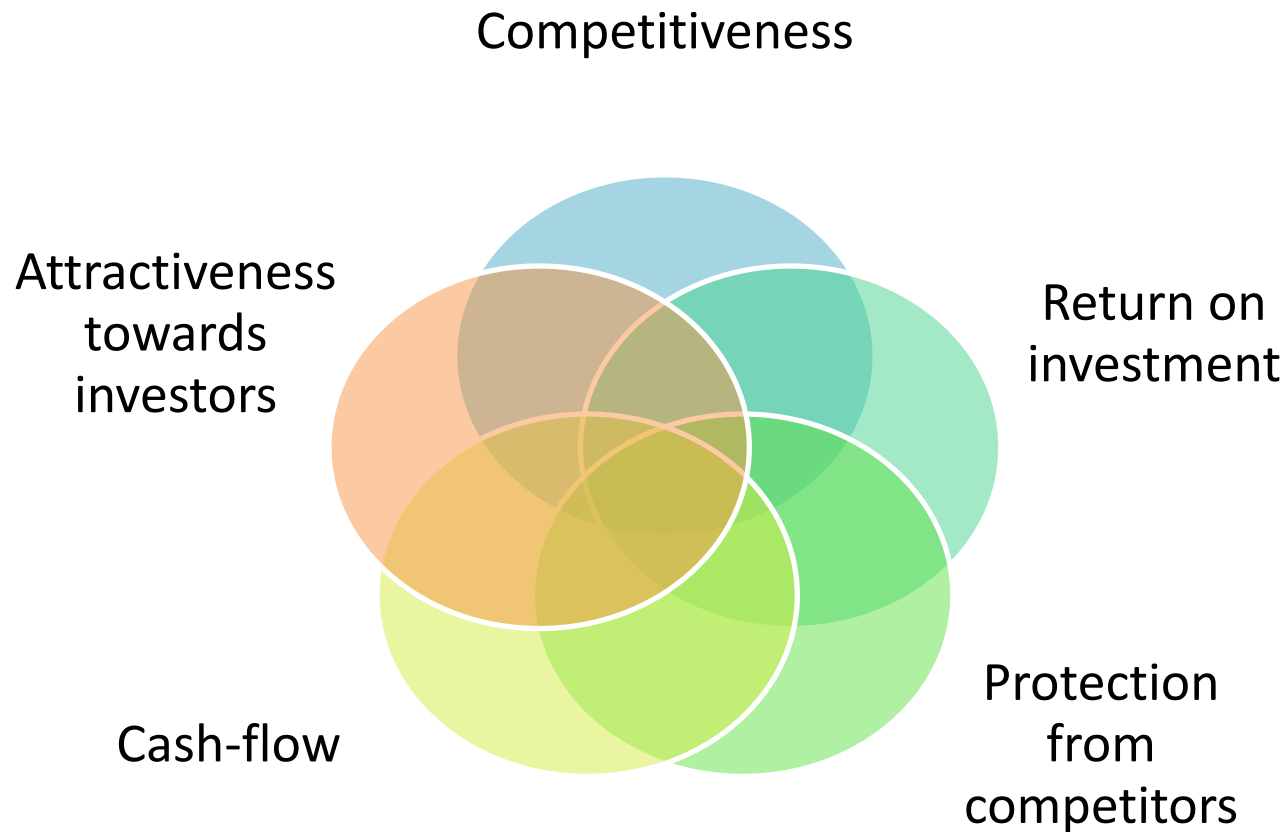
- Trademarks
- Patents
- Copyright

by filing them [in China](#): Intellectual Property is a territorial right.

**Know-how** is at stake in high-tech sectors and medical device or pharma patents are an invaluable assets

Trade fairs

# A little bit of IP awareness goes a long way



# More opportunities in South East Asia

- [Singapore's social security requirements – what a foreign employer should be aware of](#)



- [Choosing an investment model for India's medical device industry](#)



- [Emerging opportunities in Vietnamese healthcare](#)



# Q & A





## OUR GLOBAL PRESENCE



- *Dezan Shira & Associates Offices*
- *Dezan Shira Asian Alliance Members*

### CHINA

Beijing beijing@dezshira.com	Qingdao qingdao@dezshira.com
Dalian dalian@dezshira.com	Shanghai shanghai@dezshira.com
Dongguan dongguan@dezshira.com	Shenzhen shenzhen@dezshira.com
Guangzhou guangzhou@dezshira.com	Suzhou suzhou@dezshira.com
Hangzhou hangzhou@dezshira.com	Tianjin tianjin@dezshira.com
Ningbo ningbo@dezshira.com	Zhongshan zhongshan@dezshira.com

### HONG KONG

hongkong@dezshira.com

### INDIA

Delhi delhi@dezshira.com	Mumbai mumbai@dezshira.com
-----------------------------	-------------------------------

### SINGAPORE

singapore@dezshira.com

### VIETNAM

Hanoi hanoi@dezshira.com	Ho Chi Minh City hcmc@dezshira.com
-----------------------------	---------------------------------------

### DEZAN SHIRA ASIAN ALLIANCE MEMBERS

Indonesia indonesia@dezshira.com	Thailand thailand@dezshira.com
-------------------------------------	-----------------------------------

Malaysia malaysia@dezshira.com	The Philippines philippines@dezshira.com
-----------------------------------	---

### DEZAN SHIRA LIAISON OFFICES

Germany germandesk@dezshira.com	Italy italiandesk@dezshira.com
------------------------------------	-----------------------------------

United States  
usa@dezshira.com

## Our Practice in East China

### Hangzhou

[hangzhou@dezshira.com](mailto:hangzhou@dezshira.com)

+86 571 5685 9956

Suite 1001, Xuefeng Mansion, 346 Qingtai Street  
Dongcheng District, Hangzhou, China 310009

### Ningbo

[ningbo@dezshira.com](mailto:ningbo@dezshira.com)

+86 574 8733 8682

room 505, Shiji Jingmao Mansion, 158 Baizhang Road  
Jiangdong District, Ningbo, China 315040

### Shanghai

[shenzhen@dezshira.com](mailto:shenzhen@dezshira.com)

+86 532 6677 5461

Suite 1803-1805, Tian An Centre, 338 West Nanjing Road  
Huangpu District, Shanghai, China 200003

### Suzhou

[suzhou@dezshira.com](mailto:suzhou@dezshira.com)

+86 512 8686 8717

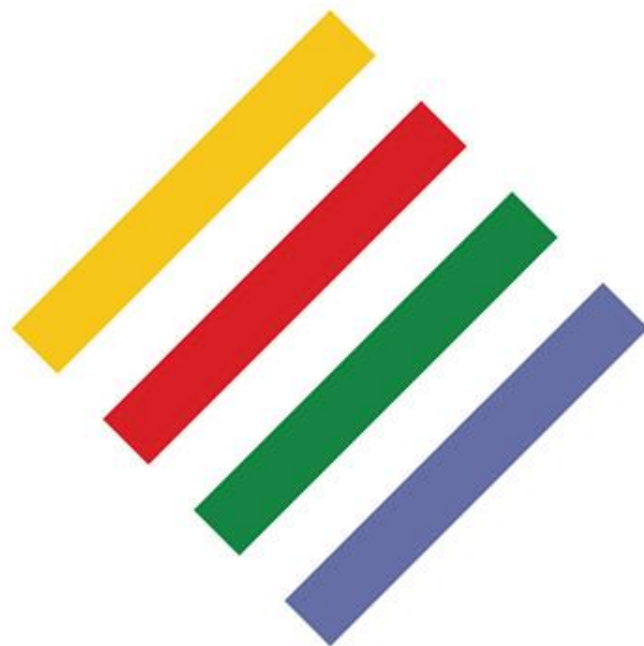
Suite 608, Xing Dong Huan  
Commerce Building,  
1508 Donghuan Road  
Wuzhong District  
Suzhou, China 215000



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