

**Report Number: QIP-ASI124451**

**Audit Date :** 26 Apr., 2012  
**Expiry Date :** 25 Apr., 2013

This report is issued by Focus Technology Co., Ltd. (Made-in-China.com) and the supervising inspectorate (SGS-CSTC Standards Technical Services Co., Ltd.) to confirm that:


**Company Name :** Xuzhou Kaixin Electronic Instrument Co., Ltd.  
 徐州市凯信电子设备有限公司  
**Showroom :** <http://kaixin.en.made-in-china.com>  
**Address :** Kaixin Mansion, C-01, Economic Development Zone, Xuzhou, Jiangsu, China  
**Product :** Ultrasound scanner

has been on site audited for the Following Scope of Activity

1. General Information
2. Quality Management System and Product Certification
3. Production Capacity & Quality Control
4. Photos



**General Comments:**

Xuzhou Kaixin Electronic Instrument Co., Ltd. is a manufacturer with 138 employees; it was established in 1997, located in Kaixin Mansion, C-01, Economic Development Zone, Xuzhou, Jiangsu, China. The buildings occupy an area of more than 6,500 square meters. Xuzhou Kaixin Electronic Instrument Co., Ltd. has its own brand “”. They have passed ISO9001:2008 and ISO13485:2003 certifications, and already have obtained EC certificates for Ultrasonic Diagnostic Instruments and RoHS certificate for Ultrasound diagnostics.



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


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# SUPPLIER ASSESSMENT REPORT

Audited Company	Xuzhou Kaixin Electronic Instrument Co., Ltd. 徐州市凯信电子设备有限公司
Audited Site:	Kaixin Mansion, C-01, Economic Development Zone, Xuzhou, Jiangsu, China
Representative of Audited Company:	Ms. Sting Shi / Foreign trading staff

Consigner of Assessment	Made-in-China.com		
Audit Type	<input checked="" type="checkbox"/> Initial Audit <input type="checkbox"/> Re-audit		
Valid Date	From 26 Apr., 2012 to 25 Apr., 2013	Verify Report	<a href="http://www.sgs.com">www.sgs.com</a>
Auditor	Simon Gao	Reviewed by	Roger Wang

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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	320301000008981
Year of established	03 Apr., 1997	Valid Date	02 Apr., 2020
Registered address	Kaixin Mansion, C-01, Economic Development Zone, Xuzhou, Jiangsu, China		
Actual address	Kaixin Mansion, C-01, Economic Development Zone, Xuzhou, Jiangsu, China		
Is the annual review done by local authority (Industrial & Commercial Bureau)?	The business was reviewed in year 2012.		
Registered capital	RMB 10,000,000		
Name of legal representative	Mr. Guozheng Bu		
Business scope	Special item: Manufacture of Class III 6823 Medical Ultrasonic Instruments and relevant equipments. Normal item: Sales of electronic products (medical equipments according to permit license), computer; Self-management and agency all kinds of goods and technology import and export business (except the state limited enterprise management or prohibit)		
1.2 Basic Information			
Contact person	Mr. Shasen	Email	<a href="mailto:info@kxele.com">info@kxele.com</a>
Phone number	0086-516-87732932 0086-516-87733758	Fax number	0086-516-87732932 0086-516-87792848
URL/Web address	<a href="http://www.kxele.com">www.kxele.com</a>		
Company type	<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Foreign trader		
Type of ownership	<input checked="" type="checkbox"/> Limited Company <input type="checkbox"/> Public Company <input type="checkbox"/> Joint Venture <input type="checkbox"/> State-Owned <input type="checkbox"/> Private Owner <input type="checkbox"/> Wholly foreign-owned enterprises		
Subsidiary company	No subsidiary company		
Products manufactured / sold scope	Ultrasound scanner		
1.3 Company Building Information			
According to: <input checked="" type="checkbox"/> Land certificate <input checked="" type="checkbox"/> Real estate certificate <input type="checkbox"/> Lease agreement			
The land occupies 4,144.9 square meters. The buildings occupy 6,520.62 square meters.			

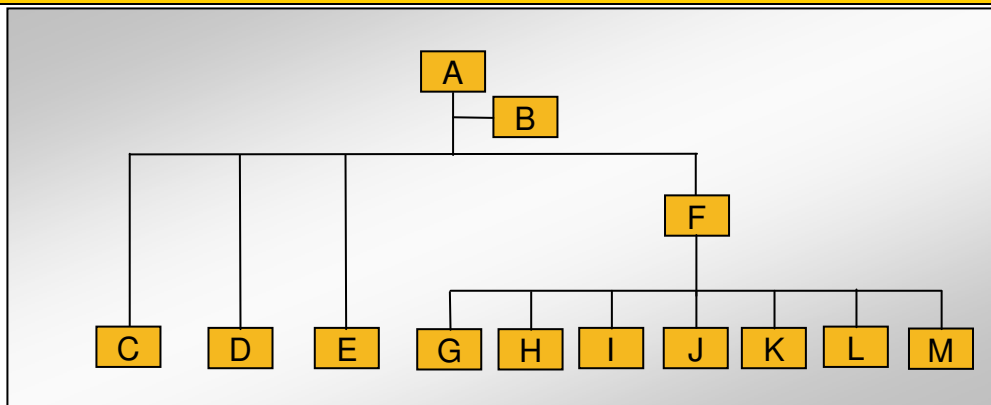
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## Section 2: Human Resources

### 2.1 Company Chart



### 2.2 Explanation of Code and Employee Details

Code	Department	Number of employees
A	General Manager	1
B	Supervisor representative	1
C	Admin Dept. and Human Resource Dept.	6
D	Quality Control Dept.	5
E	Finance Dept.	5
F	Vice General Manager	1
G	Technology Dept.	22
H	Supply Dept.	4
I	Production Dept.	27
J	Quality Dept.	4
K	Foreign Trade Dept.	15
L	Domestic Sales Dept.	38
M	After Service Dept.	9
<b>Number in total:</b>		<b>138</b>

### 2.3 Key Staff

Title	Full name	Education	Working experience for this trade / total experience
General Manager	Mr. Guozheng Bu	Junior college	/ 22 years
Technology Dept. Manager	Mr. Kai Kang	Junior college	/ 23 years
Sales Dept. Manager	Mr. Siyuan Tang	Junior college	/ 22 years

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

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## Part D: Quality Management System and Product Certification

1.1 Quality Management System and Product Certification	
<p>Has the company obtained a valid certificate for its quality management system? Such as ISO9001, QC080000 and etc.</p>	<p><b>ISO9001:2008 Certificate</b>                      No.: 04712Q10041R4M                      Scope: The Design, Development, Production and Service of KX2600 Series Full Digital B Mode Ultrasonic Diagnostic Instruments, KX280 Series Full Digital B Mode Ultrasonic Diagnostic B Mode Ultrasonic Diagnostic Instruments, KX5000 Series Full Digital B Mode Ultrasonic Diagnostic Instruments, KX2000 Series Full Digital B Mode Ultrasonic Diagnostic Instruments.                      Issued by Beijing Hua Guang Certification of Mdeical Devices Co., Ltd.                      Valid until 17 Jan., 2015</p> <p><b>ISO13485:2003 Certificate</b>                      No.: 04712Q10000035                      Scope: The Design, Development, Production and Service of KX2600 Series Full Digital B Mode Ultrasonic Diagnostic Instruments, KX280 Series Full Digital B Mode Ultrasonic Diagnostic B Mode Ultrasonic Diagnostic Instruments, KX5000 Series Full Digital B Mode Ultrasonic Diagnostic Instruments, KX2000 Series Full Digital B Mode Ultrasonic Diagnostic Instruments.                      Issued by Beijing Hua Guang Certification of Mdeical Devices Co., Ltd.                      Valid until 17 Jan., 2015</p>
<p>Is product certification done in terms of selling designation (UL for US, CCC for China, CE for Europe ...) at the company?</p> <p>I) Product certification list? if any</p> <p>II) Sample of product certification, if any (at least one of key products)?</p> <p>III) Copy of product certification sample (1-5 key products, if any)?</p>	<p><b>EC Certificate</b>                      No.: G1 11 12 52731 007                      Product: Ultrasonic Diagnostic Instruments                      Directive: 93/42/EEC on Medical Devices (MDD), Annex II excluding(4) (Devices in Class IIa, IIb or III)                      Valid from: 12 Jan., 2012 Valid until: 11 Jan., 2017                      This certificate was issued by TUV</p> <p><b>RoHS Certificate</b>                      No.: G4 10 12 52731 006                      Product: Ultrasound diagnostics                      Model(s): Full Digital Mechanical Sector Scanning Ultrasonic Diagnostic Instruments(MSU1, MSU2)                      Parameters: Rated voltage: 12V DC                      Tested according to:                      1. European Directive 2002/95/EC(RoHS)                      2. IEC 62321, Edition 1.0 2008-12 Electro Technical Products-Determination of levels of six regulated substances (lead, mercury, cadmium, hexavalent chromium, Polybrominated biphenyls, polybrominated dipheny ethers)                      Issue date: 27 Dec., 2010                      This certificate was issued by TUV</p>

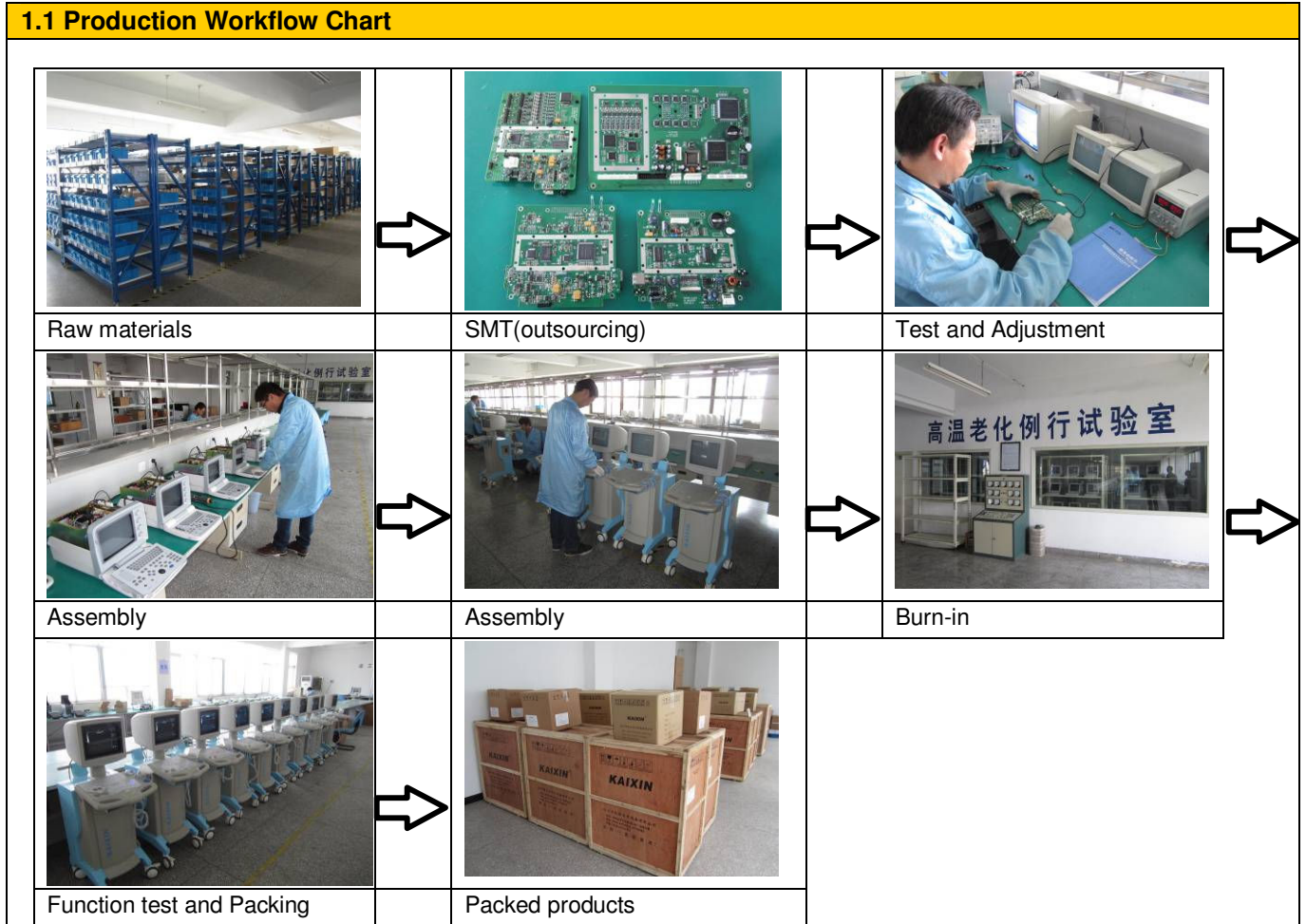
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**Part E: Production Capacity & Quality Control**


**Section 1: Production Capacity**






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**1.2 Products Situation (Top three Product Categories)**

Product Category	Capacity in Top Month	Average Capacity	Total in 2011
 <p><b>Description:</b> B Mode Ultrasonic Diagnostic Instruments</p>	398 units	312 units	3,746 Units

**1.3 Main Facilities**

Picture	Facility name	Brand or Country/Region of origin	Quantity
	Residual voltage tester	China	1
	Leakage current measurer	China	1
	Earth resistance tester	China	1

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	High-Pop tester	China	2
	Image measuring apparatus	China	1
	Oscillograph	Japan	6
	Tissue mimicking ultrasound Phantom	China	5
	Vibration tester	China	1
	High temperature Burn-in Room	China	1

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## Section 2: Production Process Control

2.1 Production Process Control		
Item	Content	Observations /Comments
1	Are the environmental conditions, such as tidiness and cleanliness being controlled and suitable for the operation performed?	<input checked="" type="checkbox"/> Very tidy <input type="checkbox"/> Normal <input type="checkbox"/> Need to improve <input type="checkbox"/> Very poor
2	Are the necessary items /documents provided at appropriate location and under control?	<input checked="" type="checkbox"/> Work Instructions /procedures <input checked="" type="checkbox"/> Workmanship standard /acceptance <input type="checkbox"/> Golden sample /Approval sample <input type="checkbox"/> Product picture <input type="checkbox"/> Verbal by workshop director
3	Are written instructions available for incoming material inspections /testing? Is the relevant record maintained?	<input checked="" type="checkbox"/> Has instructions and uniformly followed <input type="checkbox"/> Has instruction but no written records <input type="checkbox"/> Materials checked by storage staff
4	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
5	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
6	Are non-conforming units clearly marked/ segregated to prevent accidental dispatch?	<input checked="" type="checkbox"/> Marked and segregated <input type="checkbox"/> Segregated but not marked clearly <input type="checkbox"/> Not found on site
7	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 checked="" type="checkbox"/> Disuse

## Section 3: Company Development / Expansion Plans

3.1 Company Development / Expansion Plans		
Item	Company Development Action(s)	Timeframe
1	Plan to attend Hospitalar 2012 in Sao Paulo, Brazil.	22~25 May, 2012
2	Plan to attend FIME 2012 in Miami Beach, Florida, America.	08~10 Aug., 2012
3	Plan to attend MEDICA 2012 in Dusseldorf, Germany.	14~17 Nov., 2012

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Part H: Photos

Section 1: Photos of Documents

1.1 Photos of Documents

Description: Business License



Description: Land Certificate



Description: Export License



Description: Production Permit License



Description: ISO9001 Certificate



Description: ISO13485:2003 Certificate



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**Section 2: Photos of Company**

**2.1 Photos of Company and Product Sample**

**Description: Company Building**



**Description: Company Reception**



**Description: Company Hall**



**Description: Office**



**Description: Office**



**Description: Material Warehouse**



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