


# SUPPLIER ASSESSMENT REPORT

## 供应商评估报告

Audited Company: 被审核公司	Changzhou Huankang Medical Device Co., Ltd. 常州市环康医疗器械有限公司	
Representative of Audited Company: 被审核公司代表	Mr. Wenqun Mo / Production Dept. Manager 莫文群 / 生产部经理	
Audited Site: 被审核场所	Jiaoxi Industrial District, Zhenglu Town, Changzhou, Jiangsu, China 江苏常州市郑陆镇焦溪工业集中区	
Consigner of Assessment: 审核委托方	Made-in-China.com	 Company Review
Audit Type: 审核类型	<input checked="" type="checkbox"/> Initial Audit      首次审核 <input type="checkbox"/> Follow-up Audit      跟进审核 <input type="checkbox"/> Re-audit      重新审核	
Valid date: 有效日期	From Apr. 08, 2009 To Apr. 07, 2010	
Verify report: 报告验证	<a href="mailto:as.cn@sgs.com">as.cn@sgs.com</a>	
Auditor 审核员:	Roger Wang	
Reviewed by 审核:	Jeremiah Yu	

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	Audited site	: Jiaoxi Industrial District, Zhenglu Town, Changzhou, Jiangsu, China
	SGS Job No.	: QIP-ASI094146
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	Revision No.	: 05

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### 1. Company Profile 公司概况

Name of the Audited Site 被审场所名称	Changzhou Huankang Medical Device Co., Ltd. 常州市环康医疗器械有限公司		
Date of Foundation 成立日期	Jul. 08, 1988		
Registered capital in RMB 注册资金(人民币)	RMB 1,080,000		
Address 地址	Jiaoxi Industrial District, Zhenglu Town, Changzhou, Jiangsu, China 江苏常州市郑陆镇焦溪工业集中区		
Contact Person 联系人	Ms. Spring Feng / Foreign Trade Dept. Manager 冯文艳 / 外贸部经理		
Tel. 电话	0086-519-88909800 0086-519-88906800		
Fax 传真	0086-519-88906900		
E-mail 电子邮箱	<a href="mailto:hk@huankang.com">hk@huankang.com</a>		
<b>Market Distribution 市场分布</b>			
Main client 主要客户	<input type="checkbox"/> Africa	<input type="checkbox"/> Australia	<input checked="" type="checkbox"/> China
	<input type="checkbox"/> East Asia (Korea/ Japan)	<input checked="" type="checkbox"/> Europe	<input type="checkbox"/> North America
	<input type="checkbox"/> South America	<input type="checkbox"/> Other	
<b>Main Operations 主要运作</b>			
Products Manufactured/ Sold 生产/销售的产品	Disposable vaginal speculum, urine drainage bags, medical tube, disposable colostomy bags, vaginal irrigation sets, wound suction sets, ID.bracelate etc.		
Total floor size of the audited site 被审核场所的总面积	13,500 Square meters		

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## 2. Audit Checklist and result 审核检查表及结果

### 2.1 Business License 工商营业执照

Item 项目	Content 内容	Yes/ No 是/ 否	Observations /Comments 发现 /注释
2.1.1	Does the company have valid business license (the company name, address, product/ business scope complied with actual situation or not)? 被审核公司持有有效的营业执照 (公司名字、地址、产品/业务范围是否符合实际情况) 吗 ?	Yes	Refer to business license provided; it stated this company should be a trading and manufacturing business unit. The license should be valid till year 2014. The company name and address stated in business license were same as mentioned in the report. The business license indicated product scope of this company was manufacture and sale medical product, plastic product, parts and import & export business.
2.1.2	Is the annual review done by local authority (Industrial & Commercial Bureau)? 有地方行政机关(工商局)的年度审核吗 ?	Yes	Refer to business license provided; it was reviewed in year 2009.
2.1.3	Who is the corporative representative? 法人代表是谁 ?	--	Mr. Cailong Zhai (翟才龙)
2.1.4	Conclusion: is it confirmed that the audited company is a real manufacturer, foreign trader or combined? 结论: 能否确认该公司是一个制造商、贸易商或两者兼备 ?	Yes	Refer to business license provided; the company should be a combined one.

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## 2.2 Production Capacity 生产能力

Item 项目	Content 内容	Observations / Comments 发现 / 注释																									
2.2.1	What is the annual revenue (export and /or import revenues) at the company based on the data of government annual review report/ documents or other reliable financial report? 根据政府部门的年度审核报告/ 文件或其它可靠的财务报告, 该公司年度营业额 (出口和 /或出口额) 是多少 ?	Refer to financial report; the annual revenue was about RMB 12,914,127 in year 2008.																									
2.2.2	If no financial report can be showed, to calculate the annual revenue based on production report, how much is the estimated annual revenue? 如果没有以上报告出示给审核员评估, 根据生产报告的计算, 估计的年度产量是多少 ?	Please refer to 2.2.1																									
2.2.3	What is the factory floor size? 工厂面积大小 ?	5,000 square meters																									
2.2.4	Please describe the production flow involved at the factory. 请描述该工厂有关的生产流程。	Raw material → inspection → injection molding → assembly → packing → disinfect → testing → warehouse																									
2.2.5	Please describe the main facilities used at the factory. 请描述该工厂所使用的主要设施。	Refer to below Sheet.																									
	<table border="1"> <thead> <tr> <th>Facility name 设施名称</th> <th>Brand/Specification 品牌/规格</th> <th>Quantity 数量</th> <th>Number of years used 已使用的年限</th> <th>Status 状况</th> </tr> </thead> <tbody> <tr> <td>Injection molding machine</td> <td>/</td> <td>15</td> <td>/</td> <td>Good</td> </tr> <tr> <td>Bag heat-sealing machine</td> <td>/</td> <td>24</td> <td>/</td> <td>Good</td> </tr> <tr> <td>Extruding machine</td> <td>/</td> <td>7</td> <td>/</td> <td>Good</td> </tr> <tr> <td>Sterilizing equipment</td> <td>/</td> <td>2</td> <td>/</td> <td>Good</td> </tr> </tbody> </table>	Facility name 设施名称	Brand/Specification 品牌/规格	Quantity 数量	Number of years used 已使用的年限	Status 状况	Injection molding machine	/	15	/	Good	Bag heat-sealing machine	/	24	/	Good	Extruding machine	/	7	/	Good	Sterilizing equipment	/	2	/	Good	
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Sterilizing equipment	/	2	/	Good																							
2.2.6	Please gather the employee details by department. 请收集各部门人员信息	<table> <tr> <td>Chairman</td> <td>1</td> </tr> <tr> <td>Q.C. Staff</td> <td>5</td> </tr> <tr> <td>Sales</td> <td>8</td> </tr> <tr> <td>Financial Staff</td> <td>3</td> </tr> <tr> <td>Purchase Dept.</td> <td>6</td> </tr> <tr> <td>Production Dept.</td> <td>137</td> </tr> <tr> <td><b>Number in total:</b></td> <td><b>160</b></td> </tr> </table>	Chairman	1	Q.C. Staff	5	Sales	8	Financial Staff	3	Purchase Dept.	6	Production Dept.	137	<b>Number in total:</b>	<b>160</b>											
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## 2.3 Foreign Trade Capacity 外贸能力

Item 项目	Content 内容	Observations /Comments 发现 /注释
2.3.1	How many foreign trading staffs in the company ? and what are their education level/ working experience? 该公司有多少外贸人员？他们的教育水平和工作经验怎样？	Based on interview; there were 5 foreign trade staffs in the site and they had university or junior college level education.  One staff had 6-7 years working experience while the others had 1-4 years experience.
2.3.2	How about the English level (reading, writing and speaking) and foreign trading experiences based on interview and education certificate (e.g.: do they know what the LC and FOB are)? 根据面谈和教育证书，外贸人员的英语水平及外贸经验怎样？	Based on interview; the staffs had good reading and speaking capability and relevant foreign trade experience.
2.3.3	Does the trading staff clearly know the responsibilities of trading jobs? 外贸人员清晰地知道其工作职责吗？	Based on interview, they knew clearly their responsibilities.
2.3.4	Does the trading staff clearly know the product and relevant technical information? 外贸人员清晰地知道有关产品的知识和技术信息吗？	Yes. Based on interview, the trading staffs knew the basic information of product and relevant technical.
2.3.5	Does the company have successful experience of global cooperation? If Yes, please list the oversea clients' names. 该公司具有成功的全球业务合作经验吗？如果有，请列出海外客户的清单。	Yes, the company had successful experience of global cooperation.  But no oversea clients' names list provided due to business secret.
2.3.6	Does the company have oversea agency? 该公司在海外有代理处吗？	No oversea agency
2.3.7	Please mark the annual export capacity. 请备注该公司的年度出口能力。	Refer to financial report; the revenue was about RMB 4,800,000 in year 2008.
2.3.8	Conclusion: Do you think the company has foreign trading experience and competent staffs? 结论：你认为该公司是否具有外贸经验和有能力的外贸人员？	Refer to the documentations of the company and interview with the employees and management, auditor noted foreign trading experiences of the company and competent staff in the company.
2.3.9	Please describe: what does the audited company have to do before getting contract from the oversea client based on the past experience? 请描述：根据过去的经验，该公司在获得海外客户订单之前需要做些什么？	Refer to foreign trade dept. staff, the following actions would be needed: - Collect special requirements of the products for client - Sample confirmation - Confirm contract details - Production and follow up

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## 2.4 Product Research & Development Capacity 产品设计开发能力

Item 项目	Content 内容	Observations /Comments 发现 /注释
2.4.1	How many R&D staffs at the company? And what are their education level/ working experience? 该公司有多少设计开发人员? 他们的教育水平和工作经验怎样?	Based on interview; it was a manufacturing company and they had relevant experience in improving products according to requirement of client.
2.4.2	List the successful project(s), if have. 如果该公司有成功的产品项目, 请列出。	N/A
2.4.3	Is there relevant design input, output, review, verification and validation documentation available to auditor for review? 有相应的设计输入、输出、评审、验证与确认文件/记录给审核员评审吗?	N/A
2.4.4	Are the R&D staffs equipped with adequate instruments /apparatus based on the on-site observation? If Yes, please list the key facilities provided, such as equipments, software and etc. 有配备适当的仪器/ 设备给设计开发人员吗? 例如设备、软件等。如果有, 请列举主要的设备和软件。	N/A
2.4.5	Does the company have an effective design change control procedure in place? 该公司有有效的设计更改控制程序吗?	N/A

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## 2.5 Quality Management System and Product Certification 品质管理系统与产品认证

Item 项目	Content 内容	Yes/ No 是/ 否	Observations /Comments 发现 /注释
2.5.1	<p>Has the company obtained the valid certificate for their quality management system? Such as ISO9001, QC080000 and etc.            该公司是否有为其质量管理体系获得有效的认证证书？例如 ISO9001, QC080000 等。</p>	Yes	<p><b>ISO9001 Certificate</b>            Certificate No: SY 60011462 0001            Issued by TUV.            The certificate will be valid till year 2010.</p> <p><b>ISO13485 Certificate</b>            Certificate No: SY 50061913 0001            Issued by TUV.            The certificate will be valid till year 2010.</p>
2.5.2	<p>Is product certification done in terms of selling designation (UL for US, CCC for China, CE for Europe ...) at the company?            I) Product certification list? if have            II) Sample of product certification, if have (at least one of key products)?            III) Copy of product certification sample (1-5 key products, if have)?            在该公司，有针对性的销售要求做了相应的产品质量认证吗？            I) 如果有，产品质量认证证书清单？            II) 如果有，获产品质量认证的产品样品？(至少 1 个产品)            III) 产品质量认证证书副本 (如果有，1 ~ 5 个产品)？</p>	Yes	<p>CE Certificate            No.: DD 60011459 0001            Product: disposable vaginal speculums, disposable drainage bags, disposable colostomy bags, nasal oxygen cannulae, suction catheters, stomach tubes, catheters, rectal tubes, endotracheal tubes, disposable vaginal irrigation sets, feeding tubes.            Issued by TUV.</p>

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## 2.6 Suppliers/ sub-contractors Control 供应商/ 外包商控制

Item 项目	Content 内容	Yes/ No 是/ 否	Observations /Comments 发现 /注释
2.6.1	Does the company establish and implement an effective suppliers/ sub-contractors assessment procedure (which covers the acceptable criteria of supplier/ sub-contractor)? 该公司是否建立及执行有效的供应商/ 外包商评估程序(包括可接受的供应商/ 外包商标准)?	Yes	Auditor noted the company established procedures for the assessment of its suppliers and approval supplier list was provided.
2.6.2	Does the company use the results of the assessments to determine acceptable/non acceptable sources? 该公司是否根据评估的结果来决定是否采用此供应商/ 外包商?	Yes	Auditor noted the assessment reports were evaluated by the company.
2.6.3	Does the company keep the assessment report? 该公司是否保存评估报告?	Yes	Auditor noted the assessment reports were kept well.
2.6.4	Does the company retain an updated list of approved suppliers/ sub-contractors? 该公司是否有更新的合格供应商/ 外包商一览表?	Yes	Supplier list was updated in year 2009.
2.6.5	Are written instructions available for incoming material inspections /testing? 有文件化的来料检验 /测试指引?	Yes	Refer to on-site observation; auditor noted there were the documented instructions for incoming material inspection.
2.6.6	Are raw materials inspection state clearly identified? 物料检验状态有清楚地标识吗?	Yes	Refer to on-site observation; auditor noted the inspection status was marked clearly.
2.6.7	Is inspection and testing result recorded and maintained? 检验与测试结果有记录并保存吗?	Yes	Auditor noted that the company had recorded the inspection result and maintained well.
2.6.8	Are procedures of the control and release for material adequate? 控制和发放物料的程序适当吗?	Yes	Auditor noted a clear procedure for material release and recall.
2.6.9	Is non-conforming material adequately identified and controlled? 不合格的物料有适当的标识和控制吗?	Yes	Refer to the provided procedure; all non-conforming material would be refused into warehouse and marked clearly.
2.6.10	Are storage facilities and handling methods appropriate? 储存设施和搬运方法适当吗?	Yes	Yes, the material was stored in a separated warehouse.

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## 2.7 Production Process control 过程质量控制

Item 项目	Content 内容	Yes/ No 是/ 否	Observations /Comments 发现 /注释
2.7.1	<p>Are the following items /documents provided at appropriate location and under control when necessary?</p> <ul style="list-style-type: none"> <li>- Work Instructions /procedures</li> <li>- Workmanship standard /acceptance</li> <li>- Golden sample /Approval sample</li> </ul> <p>若有必要，在适当的区域有提供下面的项目 /文件？</p> <ul style="list-style-type: none"> <li>- 工作指引 /程序</li> <li>- 工艺标准 /可接受标准</li> <li>- 批准的样品</li> </ul>	Yes	<p>The company's tech. team had made the relevant work instruction and standard.</p> <p>Refer to site observation; there were documented work instructions, workmanship standard provided in the workshops.</p>
2.7.2	<p>Are the environmental conditions such as tidiness and cleanliness being controlled and suitable for the operation performed?</p> <p>环境条件，整齐清洁在受控状态之下并适合生产运作吗？</p>	Yes	Yes, the environmental condition was suitable for the operation performed.
2.7.3	<p>Is corrective action documented and followed-up?</p> <p>纠正措施有记录并有跟进吗？</p>	Yes	Auditor noted that the company had established this procedure and the record were kept well.
2.7.4	<p>Are written inspections /testing instructions available?</p> <p>有文件化的检验 /测试指引吗？</p>	Yes	The company had established the procedure for inspection and testing. There were relevant document provided to review.
2.7.5	<p>Are appropriate inspection /testing equipments available?</p> <p>有适当的检验 /测试设备吗？</p>	Yes	Refer to site observation; the company had appropriate inspection / testing equipment.
2.7.6	<p>Does the company carry out a 100% function and visual inspection?</p> <p>公司有执行 100% 功能及外观检验吗？</p>	Yes	All products were inspected 100% for function and visual inspection.
2.7.7	<p>Are non-conforming units clearly marked/ segregated to prevent accidental dispatch?</p> <p>不合格产品有清晰地标识/ 隔离以预防非逾期的使用吗？</p>	Yes	Refer to site observation; all non-conforming units were segregated and marked clearly.
2.7.8	<p>Is inspection and test result recorded and maintained?</p> <p>检验与测试结果有记录和保持吗？</p>	Yes	Refer to site observation, there were inspection and test result recorded and maintained well.

End of this section, and continue with next page. 本节结束，下一页继续。

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## 2.8 Random Product Inspection and Continuous Improvement 产品随机检验与持续改进

Item 项目	Content 内容	Yes/ No 是/ 否	Observations /Comments 发现 /注释
2.8.1	Is there a procedure to conduct random product inspection after final packaging in place? 在最后包装工序之后，是否有随机产品抽样检验程序？	Yes	Auditor noted that the company the company had established this procedure and relevant records were kept well.
2.8.2	Is there a clear procedure for handling customer complaint? 是否有清晰的程序处理客户投诉？	Yes	Refer to the relevant documentation; All customer complaint was handled by QC. Dept. staffs. They would follow up the solution.
2.8.3	Are corrective & preventive actions mechanism established and implemented effectively (including the suppliers/ sub-contractors control, incoming inspection, process control, final inspection and customer complaint)? 是否建立并有效执行纠正及预防措施机制 (包括供应商/外包商控制、来料/过程/最后检验及客户投诉)？	Yes	Auditor noted the company had documented procedure for corrective & preventive actions mechanism.
2.8.4	Can the finished/package product be traced by lot identification to the appropriate raw materials test reports? 最后的完成品能否追溯到原材料的批次？	Yes	Refer to site observation; auditor noted that the company had established this procedure for lot identification.

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## 2.9 The Company Development Plan 企业发展计划

Item 项目	Company Development Action(s) 公司发展行动	Timeframe 期限
1	A new workshop building would be put to use in this year.	2009
2	The company claimed that the target annual revenue was about RMB 30,000,000 in year 2009.	2009

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### 3. Attachments 附件

#### 3.1 Documents 文件



Description: Business License



Description: Land property certificate (copy)



Description: Foreign trader operator registration



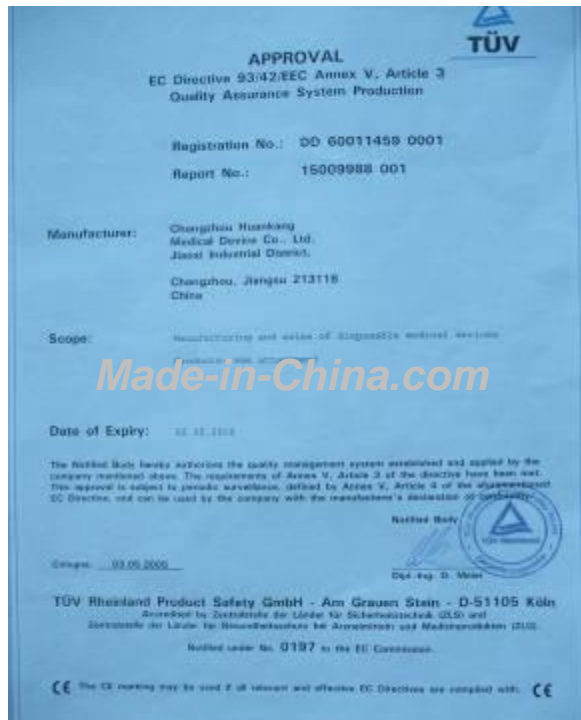
Description: CIQ Registration

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Description: CE certificate



Description: ISO13485 certificate



Description: ISO9001 certificate

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### 3.2 Photos 图片



Description: The Company Building



Description: Office Building



Description: Workshop building



Description: Raw materials warehouse



Description: Raw materials warehouse



Description: Finished product warehouse

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Description: Workshop



Description: Workshop



Description: Workshop



Description: Workshop



Description: Sterilizing equipment



Description: Testing instrument

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Description: Testing instrument



Description: Testing instrument

-- End of the Report --