

Sourcing | Freight forwarding | Quality inspection | Consolidation | Sample evaluation | Chinese Trademark

Report No.	:	STE00000001A&E	Re - Audit
Client Name	:	N/A	
Product Description	:	KN 95 disposable mask	
Base Supplier Information from Client Side:			
Supplier Name	:		
Supplier Location	:		
Participants Supplier	:		
Telephone & Fax	:		
Website	:		
Email	:		
Inspector(s) Name	:	Herbert He	
Inspection Date	:	2020.06.03	
Actual Visit Location	:	2nd Floor, No.11 Wolong Middle Road, Zhifu District, Yantai City, Shandong Province	

FACTORY AUDIT DETAIL ITEMS

A)	QUALITY CONTROL SYSTEM SCORING STANDARD	:	Please Check Next Page About Scoring Standard	
1)	VERIFICATION OF BUSINESS LICENSE	:	Conform	
2)	VERIFICATION OTHERS QUALIFICATION	:	Conform	
3)	QUALITY CONTROL SYSTEM	:	80.38	Score
4)	PRODUCTION ABILITY	:	Conform	

ADUIT OVERALL CONCLUSION	:	Excellent Factory
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SPECIAL ATTENTION	
1	The masks produced by the factory are only certified for civilian use.
2	The factory has good quality management system.
3	The factory no provided CE certificate on site for checking
4	The factory no provided established occupational health and safety management system certificate
5	The factory no provided environmental management system certificate

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A) Quality Control System Scoring Standard 评分方法		
5 Points	5分	Excellent 优秀
This element was set up and well implemented in Factory Quality Management System, the control and performance meets or exceeds SI and SI customer requirement. The Factory's control to this element is in a lead/advantage degree of this industry, couldn't require higher demand.		
工厂的质量管理体系已涵盖这一要素，管控的方式方法及实施情况达到或超过 SI 及其客户的要求，所有要求已被完整实施，工厂在这个要素的管控上处于行业内的领先地位，在行业内已不可能再提出更高的要求。		
4 Points	4分	Good 较好
This element was set up and well implemented in Factory Quality Management System, the overall control is good, but still have some minor problem in plan and execution.		
工厂的质量管理体系已涵盖这一要素，总体运行良好，但计划和实施仍存在一些小的缺失。		
3 Points	3分	General 一般
This element was set up in Factory Quality Management System, the overall control is good, but still have some major problem in plan and execution.		
Factory didn't set up documented procedure to control this element, but the process are well known for operation team and consistently executed.		
工厂的质量管理体系已涵盖这一要素，总体运行良好，但计划和实施仍存在一些主要 (Major)的缺失。		
工厂未建立文件化的程序以规定这一要素的运作，但不同员工进行同一项目的作业时，作业程序基本一致。		
2 Points	2分	Bad 差
This element was set up in Factory Quality Management System, but the overall control is poor, have many major problem in execution.		
Factory didn't set up documented procedure to control this element, inconsistent procedure executed for same process, have many major problems.		
工厂的质量管理体系已涵盖这一要素，但实施存在较多主要 (Major)的缺失，体系基本不能有效运行。		
工厂未建立文件化的程序以规定这一要素的运作，不同员工进行同一项目的作业时，作业程序不一致，存在较多的主要 (Major)缺失。		
0 Points	0分	No Control 无控制
Factory didn't set up control to this element.		
工厂没有对这一要素进行管控		
Final Score=(Sum of the individual evaluation/Number of evaluated elements)x20 总分= (评分的合计/评分项目数) X 20		
Factory classification 供应商分类:		
A: more than 80 Points 80 分以上		Excellent Factory 优秀
B: 70 Points to 79 Points 70~79 分		Good Factory 较好
C: 60 Points to 69 Points 60~69 分		General Factory 一般
D: less than 60 Points 60 分以下		Bad Factory 差

The Audit details were found as follows:

1)	VERIFICATION OF BUSINESS LICENSE
Result:	Conform / Not Conform, Refer to Special Attentions:

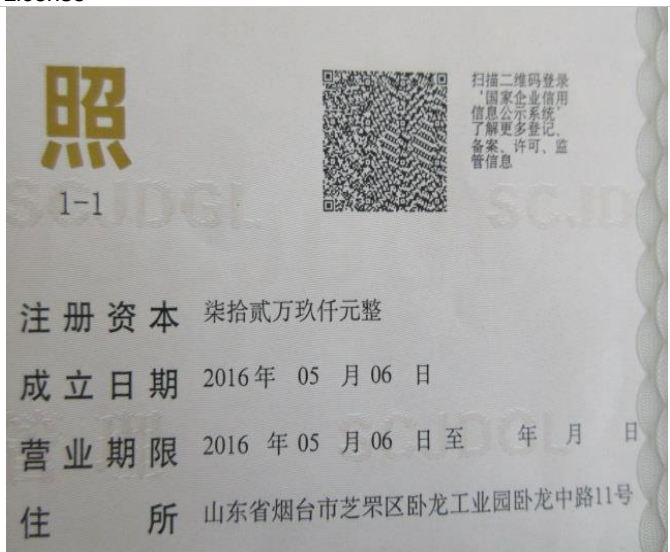
The above reflects our findings at the time and the place of inspection based on comparison of your samples selected in accordance with a previously agreed random statistical standard. This report does not discharge or release sellers/suppliers from the commercial, legal or contractual obligations with regard to quality/quantity of delivery nor does it prejudice the buyer's right of claim toward sellers or supplier for compensation for any apparent and/ hidden defects not detected during our random inspection or occurring thereafter.

Actual Factory Information:

Factory Name	: Yantai Hanyi Clothing Co., Ltd
Factory Business License Code	: 91370602MA3CA6A320
Factory Location	: 2nd Floor, No.11 Wolong Middle Road, Zhifu District, Yantai City, Shandong Province
Participants Factory	: Shirley Lee
Telephone& Fax	: 8618106384983
Website	: www.sinohanyi.com
Email	: Shirley@glorsun.com

1) VERIFICATION OF BUSINESS LICENSE REFER PHOTOS

Business License



Record of foreign trade dealers

Import and export license

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对外贸易经营者备案登记表

备案登记编号: 015021108 统一社会信用代码: 91370602MA3CA6A320

经营者名称	烟台汉伊服饰有限公司		
经营者英文名称	YANTAI HANYI CLOTHING CO., LTD		
组织机构代码		经营范围	服装服饰设计、生产、销售
住所	山东省烟台市芝罘区(芝罘工业园)芝罘大街11号		
经营场所(中文)	山东省烟台市芝罘区(芝罘工业园)芝罘大街11号		
经营场所(英文)	No. 11, Zhifang Road, Zhifu Industrial Zone, Zhifu District, Yantai Shandong Province		
联系电话	13561304159	电子邮箱	8535-6209742
邮政编码	264000	电子邮箱	zoo@hanyic.com
工商登记注册日期	2016-04-14	工商登记注册号	
依法办理工商登记的住所或经营场所以下内容			
法定代表人姓名	姜素梅	身份证件号	370581197704022228
注册资本	人民币500万元		(万美元)
依法办理工商登记的外国(地区)企业或个体工商户(独资经营)注册情况以下内容			
企业注册人姓名		有效证件号	
企业资产/个人财产			(万美元)
备注			
原备案企业备案号: 015021108			

中华人民共和国海关
报关单位注册登记证书

重要提示

报关单位应当在每年6月30日前向海关
提交《报关单位注册信息年度报告》,不
再另行通知。

海关注册编号: 37069609EW 检验检疫备案号: 3703600925

组织机构代码: 91370602MA3CA6A320 社会信用代码: 91370602MA3CA6A320

企业名称: 烟台汉伊服饰有限公司

企业住所: 山东省烟台市芝罘区烟台山路10号

企业经营类别: 进出口货物收发货人

注册登记日期: 2017年4月14日

法定代表人: 姜素梅

有效期: 长期



注册地: 烟台海关
2019年3月26日
核发日期: 2019年3月26日
001

中华人民共和国海关总署监制



R 602 building, 28 Shizuilong street,
Baiyun district, Guangzhou, China

+1 405 666 9315

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2) VERIFICATION OTHERS QUALIFICATION

Result: Conform :

QUALIFICATION DETAIL

FDA certificate	: 10063285
Quality Management system certificate	: 10418Q20677R0S

VERIFICATION OTHERS QUALIFICATION REFER PHOTOS

ISO9001:2015 Certification document



ISO9001:2015 Certification document



FAD CERTIFICATE

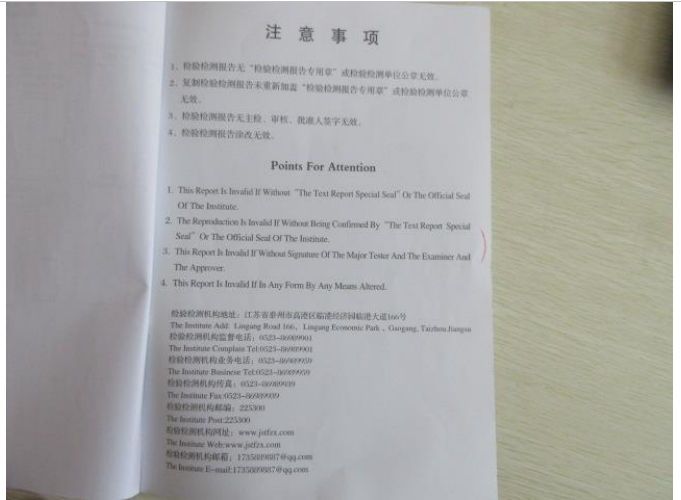
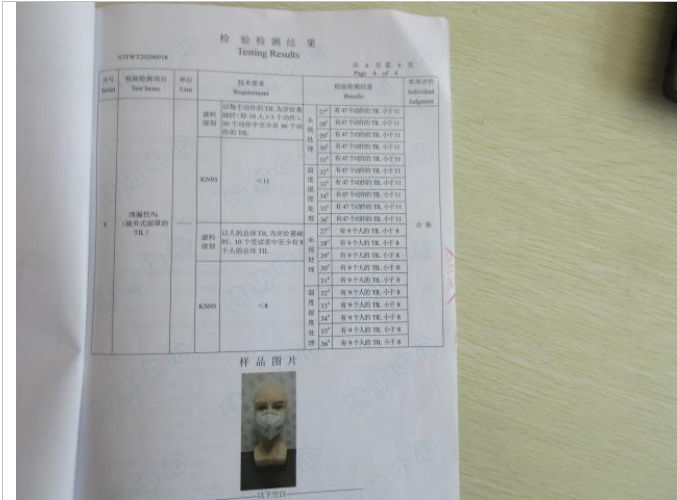


FDA CERTIFICATE

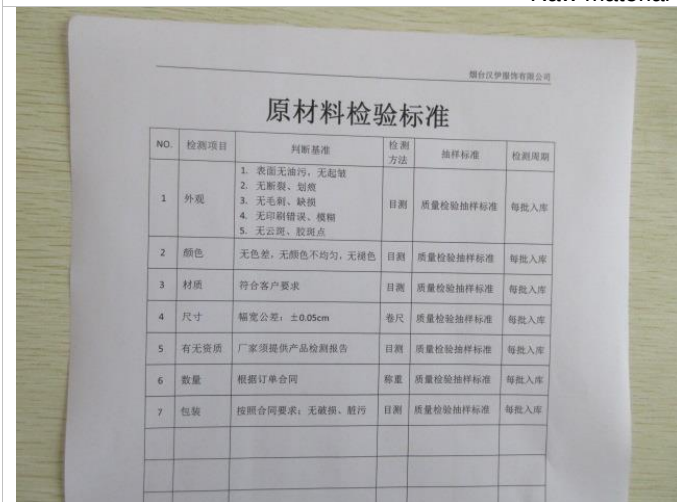


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Raw material inspection report



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3) QUALITY CONTROL SYSTEM

Items 审核项目	No	Item Description 审核内容	Score 评分	Remark 备注
QMS 质量管理体系	1	Is there a quality control system set up and implemented based on ISO9000 or other similar standard? 是否依据 ISO9000 等标准建立并实施质量保证体系	5	
	2	Are documents approved before issuing? 文件发行前是否得到批准?	5	
Management Responsibility 管理职责	1	Are the quality policies & objectives established & followed to push continuous improvement? 是否建立并应用质量方针, 质量目标以推动持续改善?	4	
	2	Are individual QC Inspector assigned for product quality inspection? 是否有专职的检验员负责产品检验?	4	
	3	Is there a supervisor/manager on all shifts? 所有的班次是否都有主管/经理?	5	
	4	Are specific authoritative person assigned to release shipment? 是否指明有权放行产品的人员?	4	
Resource Management 资源管理	1	Are training program exist to make sure operators are well trained and qualified for their job? 是否建立运行培训体系, 使员工得到充分培训以胜任他们的工作?	3	
	2	How is 5S on site? 作业现场的环境是否良好 (5S)?	5	
	3	Is there an clean/organized inspection area include adequate lighting, temperature, humidity, noise, ventilated exist in the factory? 是否有干净整洁的, 合适光照度、温度、湿度、噪声、通风等条件的检验区域?	4	
Product Realization 产品实现	1	Is there a order review system set up and implemented? 是否建立并实施合同评审制度?	4	
	2	Is there a criteria set up and implement to select supplier? 是否建立并实施供应商选择的准则?	4	
	3	Are the purchase requests delivered to suppliers clearly? 采购要求是否明确地传达给供应商?	4	
	4	Is there a supplier performance evaluation system set up and implemented? 是否建立并实施供应商绩效考核体系?	4	
	5	Are customer property include samples/materials/drawing/machine/ toolings well maintained? 是否对客户供产品 (包括样品、材料、图纸、机器、模具、工具) 进行适当的维护管理?	4	
	6	Is there an adequate engineer team to support engineering issues? 是否有适当的技术人员以处理工程技术问题?	4	
	7	Is there an engineering change control system set up and implemented? 是否建立并实施工程变更管理制度?	4	
	8	Are the record for design&change&approval well kept? 对设计开发、更改、确认的记录是否保存?	4	
	9	Is there a pre-production meeting set up to review the product specification, sample, clear all major problem before mass production, and record in meeting notes? 是否召开产前会议以在量产前评审产品规格、样品、澄清主要问题, 并记录到产前会议记录中?	3	
	10	Is there a Sample Approval procedure set up and implemented to approve sample prior to production? 是否建立度实施样品批准程序, 只有当样品批准后可以开始量产?	4	
	11	Are material/product well labeled and stored in the warehouse to prevent miss use? 是否对材料/产品进行适当的标识和储存以防止误用?	4	
	12	Are material/product proper protected to prevent damage? 是否对材料/产品进行适当的防护以防止损坏?	4	
	13	Is there an inventory control system with incoming / outgoing materials monitored and documented (location, quantity, etc)? 是否有存货控制系统以控制材料/产品的进出和存放(地点/数量等)?	4	
Product Realization (Cont.) 产品实现(续)	14	How is FIFO? "先进, 先出"的处置情况如何?	4	
	15	Are the bath of materials/products specific and traceable? 批量的构成是否明确, 可具追溯性?	4	

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	16	Does the factory set up & implement procedure to make sure that incoming raw materials, components, and or sub-assemblies conform to specifications, quality standards and US Safety requirements? 工厂是否建立并实施体系，以确保购入的原材料、零部件、或半成品符合相关规格，质量标准和美国的安全要求？	4	
	17	Are material passed IQC Inspection before pulling in warehouse? 材料是否经进料检验合格后才入库？	3	
	18	Is there a WI or drawings available to guide the material inspection? 是否按照图纸，指导书的要求等进行进料检验？	4	
	19	Is a sampling plan base on AQL or similar standard set up and implemented? 是否依据 AQL 等类似标准实施抽样检验？	5	
	20	Are DCL's (Defect Classification List) or similar being used to guide quality control? 是否有使用质量缺陷等级清单或者相似的文件以指导质量管控？	3	
	21	Are proper IQC inspection criteria set up and implement? 进料检验的项目是否充分？	4	
	22	Are IQC inspection report well kept? 是否有进料检验记录？	5	
	23	Are adequate measurement equipments available? 是否具备必要的检测仪器？	3	
	24	Are measurement equipments well controlled and calibrated according to national or industrial standard? 是否建立计量仪器的管理制度，并按国际或行业标准进行定期校准？	4	
	25	Are machines, equipment, fixtures and tools suitable to produce clients product? 机器，设备，工具是否适用于客户产品的生产？	5	
	26	Are there an equipment maintenance and protection standards set up & implemented? 是否建立并实施合适的机器设备保养检修标准？	3	
	27	Are there a tooling maintenance and protection standards set up & implemented? 是否建立并实施合适的模具维护保养标准？	3	
	28	Are adequate production capacity available for SI order? 是否具备必要的生产能力以生产松实公司的产品？	4	
	29	Are WI proper prepared and show in production line to guide the production run? 是否编制并在生产线展示必要的作业指导书以指导产品生产？	3	
	30	Are the working standards specific? 是否明确作业应达到的标准？	4	
	31	Does the factory use defect samples in the production area to show examples of common defects? 是否在产品生产区域展示缺陷样品来说明产品的常有缺陷？	3	
	32	Are there quality notification boards on the production floor to bring notice to potential issues? 是否在生产现场用公告板等形式警示潜在的不良现象？	3	
	33	Is there a FPA (First Product Approval) or silimar system set up for daily production run? 是否建立首样检验制度？	4	
	34	Are products passed IPQC Inspection before pulling in warehouse? 产品是否经制程检验合格后才入库？	5	
	35	Are proper IPQC inspection criteria set up and implement? 制程检验的项目是否充分？	4	
	36	Are IPQC inspection report well kept? 是否有制程检验记录？	4	
Product Realization (Cont.) 产品实现(续)	37	Are products passed PSI Inspection before shipment? 产品是否经出货检验合格后才出货？	5	
	38	Are proper PSI inspection criteria set up and implement? 出货检验的项目是否充分？	4	
	39	Are PSI inspection report well kept? 是否有出货检验记录？	5	
Measurement, Analysis & Continual Improvement 测量，分析与持续改进	1	Are non-conforming raw materials, in-process product and finished product properly segregated and identified at all stages? 不合格的原材料、半成品和成品是否都已经被适当隔离和标识？	5	
	2	If non-conforming materials or product are reworked, do records show that they have been re-inspected and confirmed to comply with specifications? 如果不合格品被返工，是否有记录以证明它们有经过重检并符合相关规格？	3	
	3	Are there any corrective and preventive actions for non-conforming products? 对不合格品是否实施纠正和预防措施？	5	

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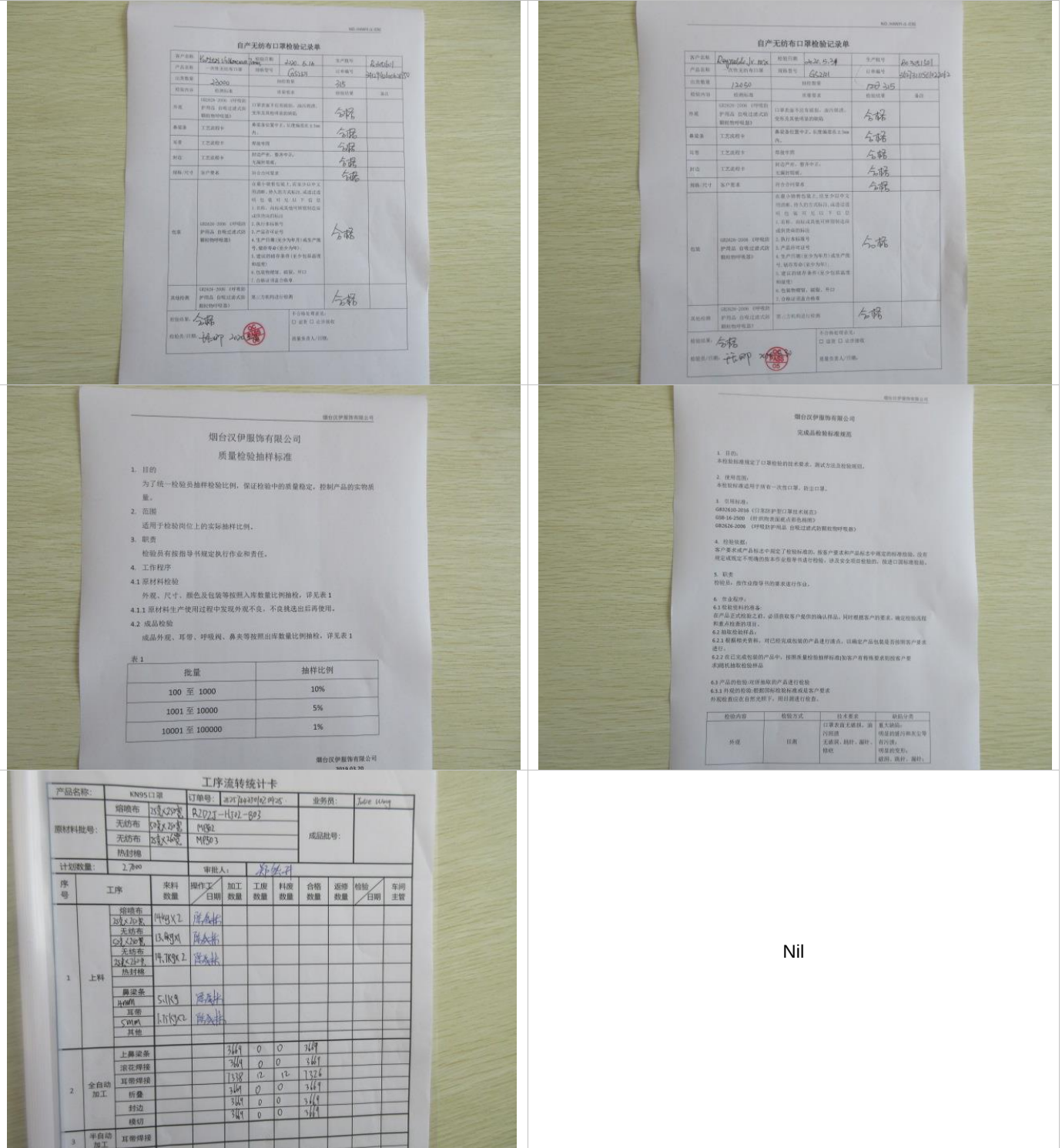
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	4	Is there a period performance review system set up and implemented to push the continuous improvement? 是否建立并实施定期的绩效评审体系以推动持续改善？	4	
Final Score=(Sum of the individual evaluation/Number of evaluated elements)x20 总分=（评分的合计/评分项目数）X 20			80.38	

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3) QUALITY CONTROL SYSTEM REFER PHOTOS



Nil

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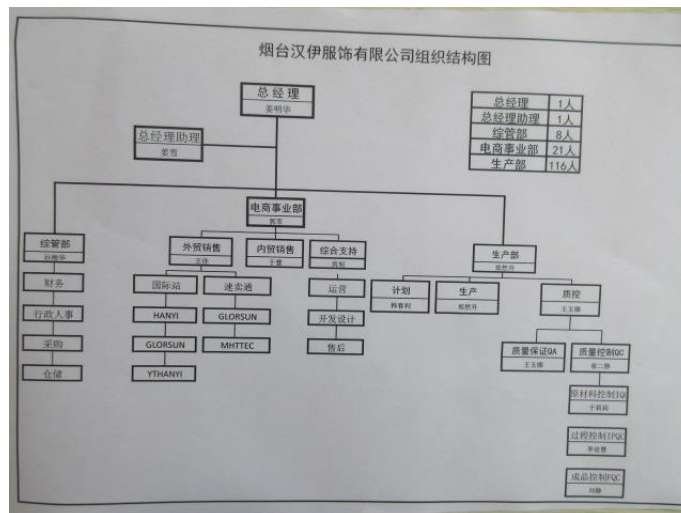
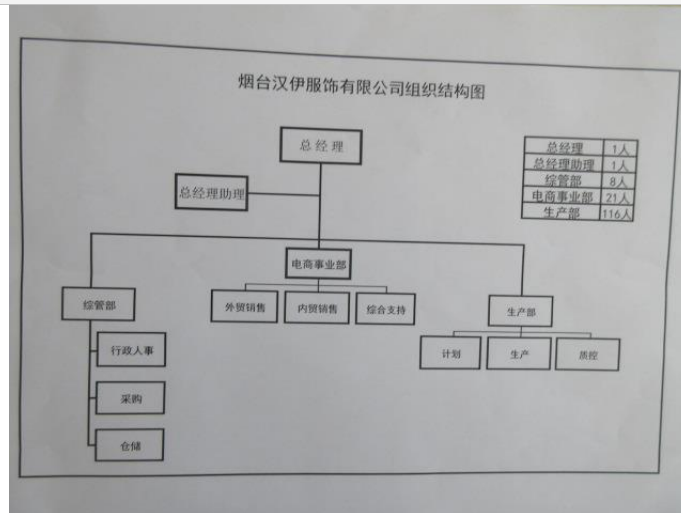
4) PRODUCTION ABILITY

Result: Conform :

Factory Production Capacity Assessment Profile				
Off Site Survey			√	On Site Confirmation
Ownership	Limited liability company		Date of establishment	2016.5.6
Bank Reference	A		Factory Area(m²)	1,627 m²
Major Customers (Per Country/Area)	Trade secret			
Order Completion Lead Time(Days)	10-15days		Sample Completion Lead time (Days)	3-5days
Production Capacity (Monthly)	6600,000pcs		Minimum Order Quantity Requirement	10,000pcs
Annual Volume (US\$)	USD 12,00000			
Product	Sales volume	Capacity	Domestic rate	Export rate
KN95 mask	60,000,000pcs	200,000/day	0%	100%
Washable mask	30,000,000pcs	100,000/day	0%	100%
Major Manufacture Equipment & Process				
Type	Supplier or Brand		Quantity	Capacity
KN95 full automatic mask machine	/		3	/
Filter cutting machine	/		1	/
Ultraviolet rays machine	/		1	/
Packed machine	/		3	/
Testing Equipment				
Type	Supplier or Brand		Quantity	Testing range/ Standard
/	/		/	/
Employee Count				
Position	Quantity		Position	Quantity
Engineering Staff	2		Management	5
QA/QC Staff	2		Workers	38
Sales	28		Total	66

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Factory Organization Chart (Could show the picture)



4) PRODUCTION ABILITY REFER PHOTOS

Factory gate



Factory building



Factory name

Factory room



Office area

Office area



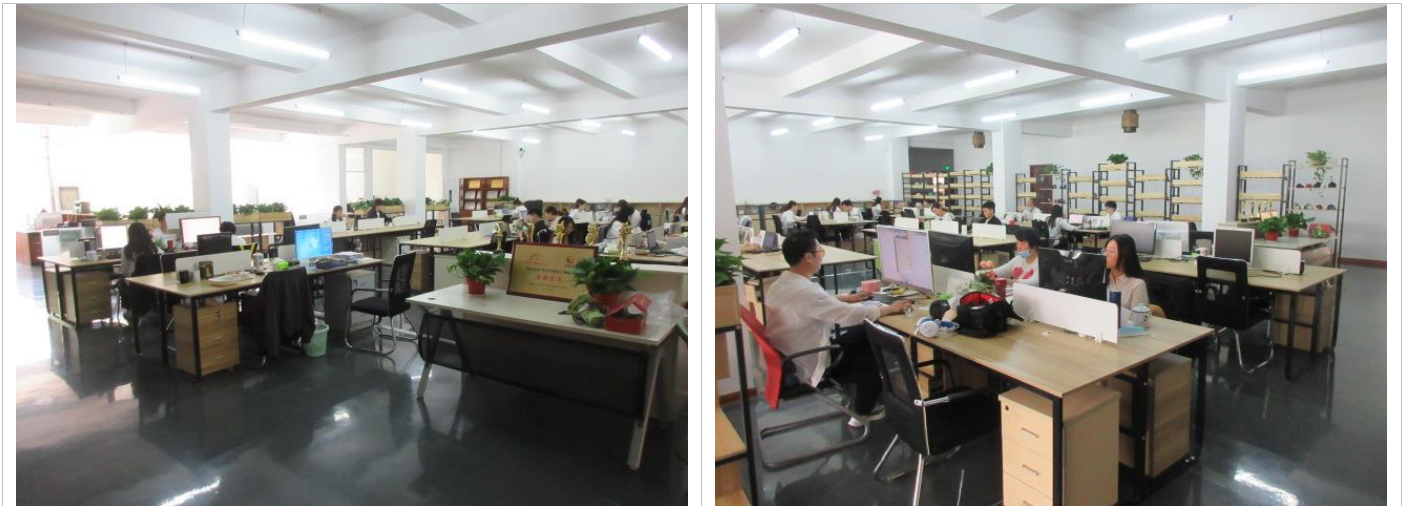
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Office area



The CEO's office



Finance department.



Finance department



Purchasing department.



The meeting room



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Customer department



Exit



The production line



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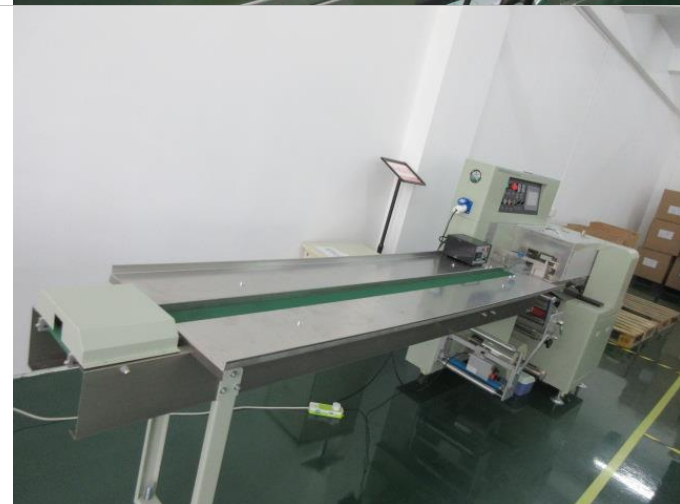
The above reflects our findings at the time and the place of inspection based on comparison of your samples selected in accordance with a previously agreed random statistical standard. This report does not discharge or release sellers/suppliers from the commercial, legal or contractual obligations with regard to quality/quantity of delivery nor does it prejudice the buyer's right of claim toward sellers or supplier for compensation for any apparent and/ hidden defects not detected during our random inspection or occurring thereafter.

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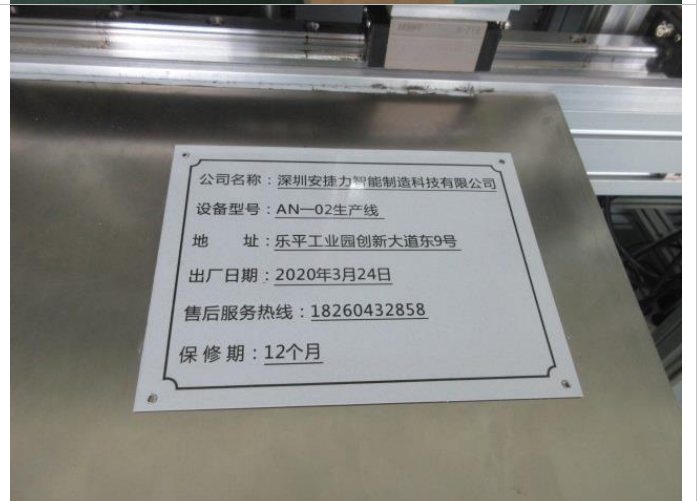
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**OTHERS REFER PHOTOS**

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 R 602 building, 28 Shizuilong street,
Baiyun district, Guangzhou, China

 +1 405 666 9315

 www.sourceguy.com

 info@sourceguy.com

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