

INSPECTION REPORT

Factory Audit

Report No. : H-XXXXXX

INSPECTION INFORMATION				
Client	XXX			
Factory Name	XXX			
Factory Address	XXX			
Contact Person	XXX	Telephone	XXX	
Mobile Phone	XXX	Fax.	XXX	
E-mail	XXX	Web:	XXX	
Date of Audit	XXX	Auditor(s)	XXX	
Audit Stage	Initial Audit Follow-up Auc	lit 🗌 Re-Audit	(Previous report No.:)	
Audit Regulation	GWI-PE-TQA-020-HQT			
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Participators from	n the factory:				
Name	Department	Position	Name	Department	Position
Mr. Yang Ximing	Production	Manager	Mr. Tang Haifang	QA	Quality supervisor
		A A			

AUDIT RESULT SUMMARY					
	Audit Criteria		Actual	Percent	Grade
Part 0	General Information	Score	Score		
Part 1	Workshop/warehouse and other infrastructure resources	40	26	65%	С
Part 2	Production machines/Equipment/Fixtures	35	29	83%	В
Part 3	Production process control	60	41	68%	С
Part 4 Purchase and subcontract		15	11	73%	С
Part 5 Packing, handling and storage		40	17	42%	D
Part 6 Training, knowledge, skill, and experience		45	36	80%	В
Part 7 Inspection/testing and quality control		65	44	68%	С
Part 8 Control of nonconforming product		30	23	77%	С
Part 9	Documentation of management / records control	35	20	57%	D
Part10	Management authority and managers in high-level	40	30	75%	С
	OVERALL CONCLUSION (GRADE):	D			
Remark					

Approved by HQTS Supervisor:

	SPECIAL ATTENTION POINTS		
No.	Problem Description	Ма	Min
1	Facilities, Equipments and Hygiene:	\boxtimes	
	-Incoming warehouse is not enough to accommodate the silicone materials, some of them were		
	open storage, floor and wall surfaces are dirty, and windows are not close.		
	-Semi-finished warehouse, the factory had properly store most bulk products, but some of the		
	bottles, silicone bras were placed near the drain.		
	-Finished goods warehouse, export cartons were placed on the floor directly, 90% squashed/		
	damaged export carton.		
	-The factory does not control temperature and humidity conditions in warehouse.		
	- Provisions made to prevent infestation by parasites, insects, rodents or birds are not available	and a start of the	
	on warehouse or producing area.		
	- Clean workshops are not strictly implementing activities to prevent contamination.		
	- No washing/ disinfection facilities are provided in workshop.		
	- The factory does not separated and well stored the chemicals such as painting, thinner,		
	detergent, etc.		
	- Personal hygiene, masks, gloves are not available on necessary producing process. Hairs are		
	not wrapped inside hat. And women are permitted to wear earring and finger ring.		
2	Procedure:	\boxtimes	
	-The factory dose not establishes procedures or instructions about hygiene management to		
	ensure appropriate materials, storing, producing, and transporting conduction.		
	- Inspection procedures are not available during audit		
	- Training procedure and training plan are not including hygiene		
	-The factory does not establish related procedures about the raw materials sampling; equipment		
	cleaning or product recall measures.		
	- Personal hygiene, skin disease, respiratory diseases are not regularly checked and maintain		
	records.		
3	Manufacturing	\boxtimes	
	-Parameters such as temperature, pressure on key equipment/ process were not regular		
	monitored/ verified.		
	- Necessary equipments are clean but do not sterilize.		

	- Liquid silicones were mixed stored with lubricating oil without separation. Some of the			
	semi-finished products do not properly stored.			
4	Quality Management	\square		
	-Data for analysis of raw materials and packaging kept only three months instead of a general			
	requirement to keep a period of not less than one year; data for samples of finished products are			
	kept only 3 months either.			
	-The factory dose not establishes a documented recall system to handle the customer			
	complaints.			
GEN	ERAL COMMENTS		1	
	XXX. was found in 2007 and they mainly produced all types of silicone products: silicone feeding bottles,			
	baby nipples; silicone kitchen wares; silicone bras, nipple covers, etc. and the factory had	achieve	d ISO	
	9001:2008 and ISO14001:2004 since 2009.	A CONTRACTOR		
	During audit, the factory had set up a normal quality management system to control the produ	ction. E	But the	
	factory did not establish a strict procedure according hygienic management to monitor producing. An			
	manufactory/ quality records are missing or very simply.			

	FOLLOW UP SUGGESTIONS		
	For factory:		
1	To establish and implement procedures to monitor the hygiene.		
2	To establish and implement recall procedures		
3	To well store all the raw materials, semi-finished products and finished goods.		
4	To establish related procedures about the raw materials sampling.		
5	To clean and sterilize the producing location and key equipments before production.		
6	All records and samples should be well stored not less than one half product life.		
7	7 To increase washing/ disinfection facilities in clean workshop.		
	For client:		
1	Suggest performing the follow up audit for this factory.		

Audit details are as follows:

Part 0 General Information

• Ownership of the factory:

Dublic Private Domestic-investment limited Sino-foreign joint venture Wholly foreign-owned

History:

Factory founded at:				
Product (Series)	From (Year)	To(Year)	Output Value Per Year About	
Silicone materials	1993	2002	Can't provide	
Silicone ladies products	2002	Present	Can't provide	
Silicone feeding products	2008	Present	Can't provide	
Production areas a	Production areas and buildings:			

Number of production areas:	Total 1 production areas	
Location and Function of the area(if more than one area):		
Number of buildings:	5 production buildings	
Total area in square meters:	~6,000m2	

Manpower

Staff	Total number	Percentage	Staff	Total number	Percentage
Manager	20	5.4%	Technical personnel	36	9.6%
Q.C	35	9.4%	Workers	263	70.2%
Others	20	5.4%	Total number of staff	374	100%

A

Production planning per day:

One shift:hours / per shift for Dept.:	
Two shift: <u>12</u> hours / per shift for Dept.:	All production process
Three shifts: hours / per shift for Dept.:	

Production capability (if the data was available) :

Product	Daily Output (pcs)	Monthly Output (pcs)	Remark
Can't provide			

Typical Production Lead Time (From reception order to finish packing) :

Product Name	Lead Time (Days)
Silicone ladies products	3-5
Silicone feeding products	5-7

Main countries or areas to export per year (if available):

Product	China (%)	Asia (%)	Europe (%)	America (%)	Africa (%)	Others (%)
Can't provide						
Technical ca	anability of des	ianina the proc	luct:			

Technical capability of designing the product:

• Technical capability of production:

\boxtimes	Produce the products	Assemble the products

Subcontract the order to other factory

Main Production Process Description

Process	In-house	Su	b-Contract	F	Process		In-house	Sub-Contract
Silicone bra				Silic	cone bo	ttle	\boxtimes	
Main production ma	chines/equi	oment	s:					
Machine N	lame		Numbers	;	Mach	nine Nam	е	Numbers
Can't provide								
Certificated by third	party:							
Typology of Audit / Cert	ficate	Date	& period of	validity		Organiz	ation of cert	ification
ISO 14001:2004		2009	9.17- 2012	.9.16		EACC		
ISO9001:2008		2009	9.17- 2012	.9.16		EACC		
Inspected by the clie	ent or third p	oarty's	:					
Never Eve	, but not ofte	n	Ofter	า				
Inspection orga	nization		Client	3-party		In	spection Da	te
		4						

No.	Check and Audit Points	Grade
Part	1 Workshop/Warehouse and Other Infrastructure Resources	
1.1	Is the layout of the factory /workshop/warehouse reasonable and benefiting the production?	В
1.2	Do there exist some pollutants like soot, dirt, acid mist and etc. around the factory /workshop /warehouse that would affect the production?	С
1.3	Are the buildings of workshops/warehouse fit for the production and are they maintained adequately?	D
1.4	Are the workshop/ production lines maintained cleanliness, tidiness and suitable for the production?	С
1.5	Can the factory obtain adequate outer resources including water, electric power, and etc. To achieve the requirements of production?	С
1.6	Are the inner infrastructures such as water supply system, power supply system suitable maintained and under good condition?	В
1.7	Does the factory have the spare/alternative electric power, water and etc. supply system to sustain the production in case of outer supplies ceasing caused by accident?	В
1.8	Are electronic communicated apparatus such as telephone, fax and other office apparatus such as computer, copycat available in the factory?	В
Part	2 Production Machines/Equipment/Fixtures	
2.1	Does the factory have adequate kinds/quantities of machines/equipment/fixtures for the production of intended products?	В
2.2	Does the factory implement procedures to maintain the machines/equipment/fixtures regularly to ensure their continuing process capability?	А
2.3	Does the factory calibrate the machines/equipments interval or adjust prior to use which needed to ensure the accuracy/precision?	В
2.4	Do operators or specified person check/lubricate/clean the machines daily in accordance with the instruction manual of the machine?	В
2.5	In case of the some problems of machine/equipment occurred , does the operator stop using the machine until it been repaired?	В
2.6	Based on observation on-site, are the machines/equipment/fixtures in a good condition?	В
2.7	Based on observation of machines/equipment/fixtures and the products worked out, is the accuracy/precision of them conform the requirements of production?	В
Part	3 Production Process Control	
3.1	Are the arrangement of production plan is reasonable and in accordance with the requests of orders and production ability?	В
3.2	Does the factory adopt a proper way to make on-the-spot workers understand the concrete requirements of orders/ plans and the amendments of production?	В
3.3	Does the factory formulate operating instructions for key working process where the absence of such instructions could adversely affect quality?	В
3.4	Do the operating instructions correctly stipulate the process parameters, product characteristics and workmanship criteria?	В
3.5	Are the required operating instructions present on related workstations, and does the operation of workers conforms to the requirement of instructions?	В
3.6	Does the factory adopt adequate ways to monitor and control the suitable parameters and product characteristics on key process?	D
3.7	Do workers operate correctly and meet the requirement in the process where without or no need of operating instructions?	С
3.8	Does the production flow operate smoothly? Are there any serious bottleneck affects the production lead times?	В
3.9	Are those raw materials, semi-finished products, finished products in workshop arrayed/stock in	В

No.	Check and Audit Points	Grade
	good order and carefully protected to avoid confused or damaged?	
3.10	Does the factory adopt a suitable way such as marking, labeling and etc. to identify the raw materials/semi-finished products/finish products to avoid confusion?	С
3.11	Does the factory adopt a suitable way such as marking, labeling and etc. to identify the raw materials/semi-finished products/finish products/samples for specified client to avoid it confusion with other clients?	С
3.12	When some problems occur, can operators trace back relevant product according to the identifications and records?	С
Part	4 Purchase and Subcontract	
4.1	Does the factory have established and maintained procedures to evaluate and select suppliers to ensure that the production materials purchased conform to specified requirements?	В
4.2	Dose the factory prescribe the specification such as type, grade, quality and etc clearly on purchasing document?	В
4.3	Does the factory monitor the quality of purchasing goods and adopt adequate actions such as changing supplier in case that the goods provided by the supplier often not conform to the requirement?	с
4.4	Does the factory have established and maintained procedures to evaluate and select subcontractors on the basis of their ability to meet subcontract requirements?	N/A
4.5	Does the factory stipulate the detail date of specifications such as technical parameter, quality requirement, delivery date and etc. on subcontract?	N/A
4.6	Does the factory adopt an adequate way to trace and monitor the situation of the subcontract products during them being producing to ensure they conform to the requirement?	N/A
Part	5 Packing, Handling and Storage	
5.1	Does the factory use adequate method/material to pack the products to ensure conformance with specified requirements?	С
5.2	Does the factory use proper methods/containers/utensils for handling and delivery of product to prevent damage or deterioration?	D
5.3	Does the factory have sufficient warehouse /stock rooms to meet the requirement of goods storage in accordance with the production capability and product schedule?	С
5.4	In case of storing the product in the open air when short of warehouse capacity, dose the factory use special prevention actions to prevent the product from raining and sun burning?	D
5.5	Are the Warehouses keeping clean, bulk goods piled up suitably?	D
5.6	Does the factory adopt appropriate methods to prevent the stored goods from improper pressing, crashing, sun burning, leaking, mildewing or insects bite?	D
5.7	Does the factory adopt a suitable way such as making, labeling, and etc. to identify stored goods especially for specified client's goods to avoid confusion?	В
5.8	Does the factory exist an appropriate system or methods for controlling receipt and dispatching from stock area? Can the factory insure that the quantity of goods is right no matter in receipting, dispatching, and loading?	С
Part	6 Training, Knowledge, Skill, and Experience	1
6.1	Does the factory exist and implement training procedures / plans to train personnel performing activities affecting quality?	В
6.2	Have those related operators been trained/explained the main points of requirements/operations for every client's orders prior to operation?	В
6.3	Base on observation or exam on-spot, are those workers well-trained and skillful for the assigned work?	В
6.4	Are the workers with good attitude regarding to production, quality requirements, inspections and re-work action?	В
6.5	Has the factory ever provided enough courses of product standard and inspection/testing to the Q.C/inspectors?	В

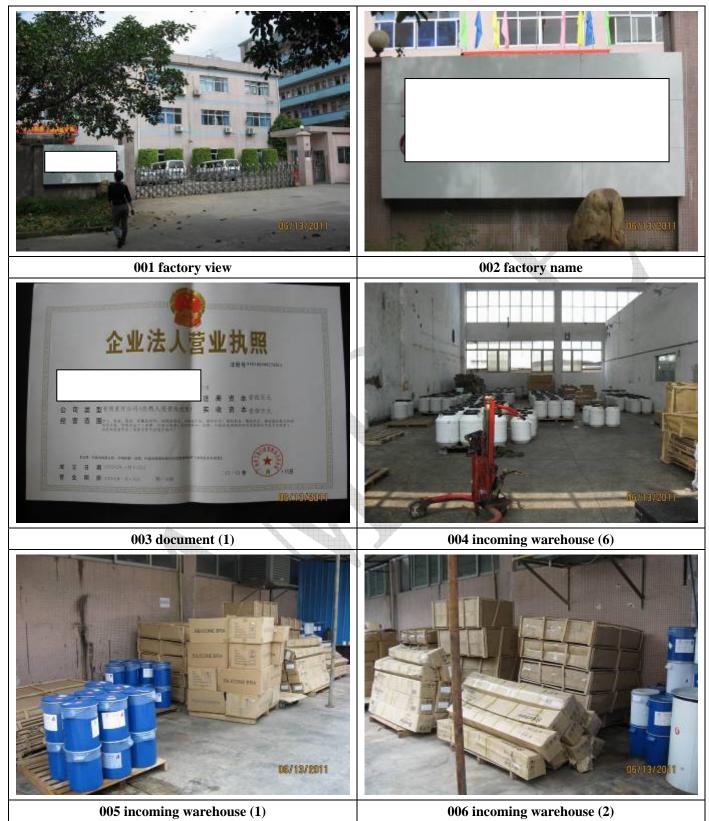
Scoring: A=Outstanding=5 B=Good = 4 C=Acceptable =3 D=Below requirement=1 E=Absent or Not-available =0 N= Not Applicable (Not be scored)

No.	Check and Audit Points	Grade
6.6	Are there records of training the operators and inspectors kept in the factory?	В
6.7	Base on observation or exam on-spot, does those Q.C/inspectors have suitable knowledge/ability /skill to meet the requirements for their assigned work?	В
6.8	Do the leader of Q.C department /Q.C/ inspectors have good working attitude and deal with quality problems objectively?	В
6.9	Are the leader of Q.C department, managers of workshop with good attitude regarding to the 2 nd and 3 rd part's inspection or audit?	В
Part	7 Inspection/Testing and Quality Control	
7.1	Does the factory carry out receiving inspection/testing process when receiving or before using the purchased materials and subcontracted product?	В
7.2	Are the frequency, criteria and method of receiving inspection reasonable and in accordance with the specified requirement or documented procedures/plans?	С
7.3	Does the factory set up adequate number of inspect/testing stations on suitable process of production to ensure that the quality of product conformed to the specified requirement before being released?	В
7.4	Do the inspectors of the factory carry out the in-process inspections compliance with reference standards/operation instructions and/or documented procedures?	В
7.5	Does the factory designate an adequate number of inspectors to perform the in-process inspection and testing?	В
7.6	Does the factory carry out the final inspection for all batches of products in accordance with the final inspection standard?	С
7.7	Does the factory formulate the final-inspection standard for all products? Are all related parameters/characteristic/criteria and inspection methods stipulated on the standard?	D
7.8	Does the factory ensure that only when the result of final inspection meet specified requirement or standard, the product can be released?	С
7.9	Does the factory equipped with adequate types and quantities of inspection and testing equipments/ apparatus for the receiving, in-process and final inspection?	В
7.10	Does the factory establish and implement procedures to calibrate and maintain inspection, measuring and test equipments?	В
7.11	Are the inspection/ measuring and test equipments used on -site well maintained and calibrated?	С
7.12	Do those used conformity samples have been confirmed by client or appointed manager?	В
7.13	Does the factory adopt a proper way to identify, preserve and use the samples?	С
Part	8 Control of Nonconforming Product	
8.1	When finding nonconforming product, does the factory identify and segregate them immediately?	В
8.2	Does the factory make any record when finding and disposing the nonconforming products?	В
8.3	Have those nonconforming products been disposed properly such as reworked, repaired and etc before being reused?	В
8.4	Does the factory carry out re-inspection/testing for all reworked and repaired products?	В
8.5	When non-conformity continuously occurred or a series of nonconforming product were found, does the factory analysis the reasons and implement related corrective or preventive actions to eliminate the cause of nonconformities?	В
8.6	Does any statistics be done for the rate of non-conformity, and is the rate of non-conformity ascending or descending?	С
Part	9 Documentation of Management / Records Control	
9.1	Does the factory have document such as management manual to describe the quality management system?	В
9.2	Dose the factory has document to define the responsibility, authority of the personnel who	С

Scoring: A=Outstanding=5 B=Good = 4 C=Acceptable =3 D=Below requirement=1 E=Absent or Not-available =0 N= Not Applicable (Not be scored)

No.	Check and Audit Points	Grade
	manage, perform and verify work affecting quality?	
9.3	Does the factory has established and documented min management procedures which affecting quality strictly?	D
9.4	Does the factory have procedure for collecting, filling, storage, maintenance and etc of quality records?	С
9.5	Does the factory preserve related quality records (especially for inspection records, disposing the nonconforming records, calibration of testing equipment records) in an adequate period?	С
9.6	Are those records identified, indexed, filed and maintained well?	С
9.7	Are the data and information recorded in those quality records clear, integrated, veracious and signed by related recorder?	С
Part	10 Management Authority and Managers in High-Level	
10.1	Can the manager of related department/workshop implement the defined responsibility, authority, duty well?	С
10.2	Does the department of quality control get enough right for assigned work and perform its obligation normally and independently?	с
10.3	What about the knowledge, experience and ability of the managers in high-level	В
10.4	What is the attitude of the managers in high-level for client's requirement, inspection, quality, nonconforming product and corrective action?	В
10.5	What is the attitude of the managers in high-level for this audit?	В
10.6	Does the factory respond the customer's complaint in time and deal with it correctly?	В
10.7	When problems on trade appear, is the factory willing to undertake their relevant responsibility?	В
10.8	When the customers require compensation, is the factory willing to indemnify the client's lost?	В

PHOTO ATTACHMENT





011 incoming warehouse- oil mixed stored with silicons

012 incoming warehouse- damaged package















053 padding workshop (1)

054 padding workshop (2)





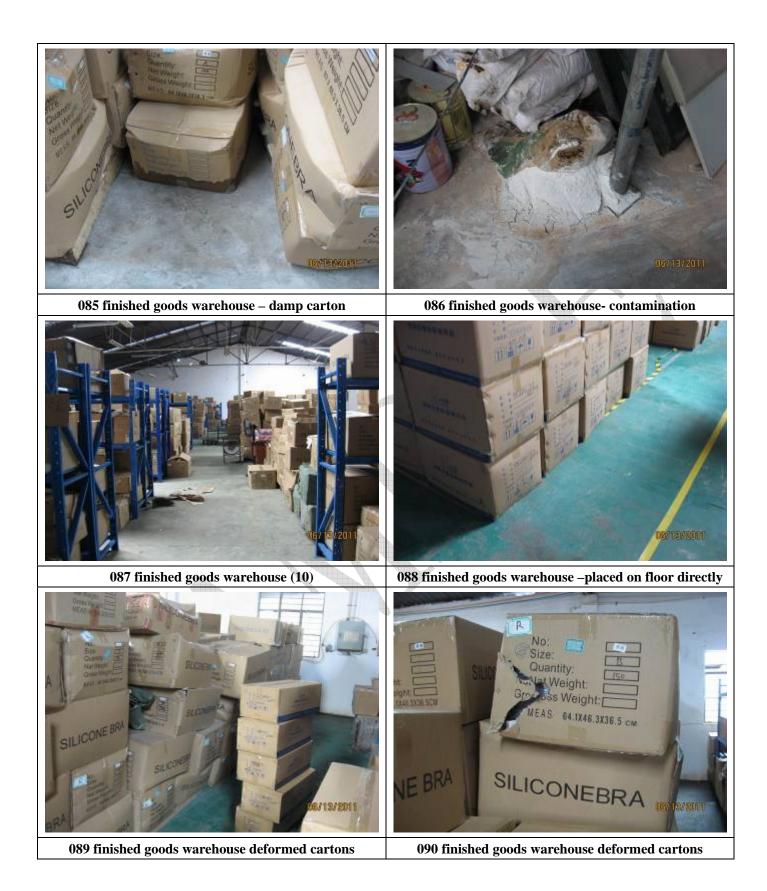




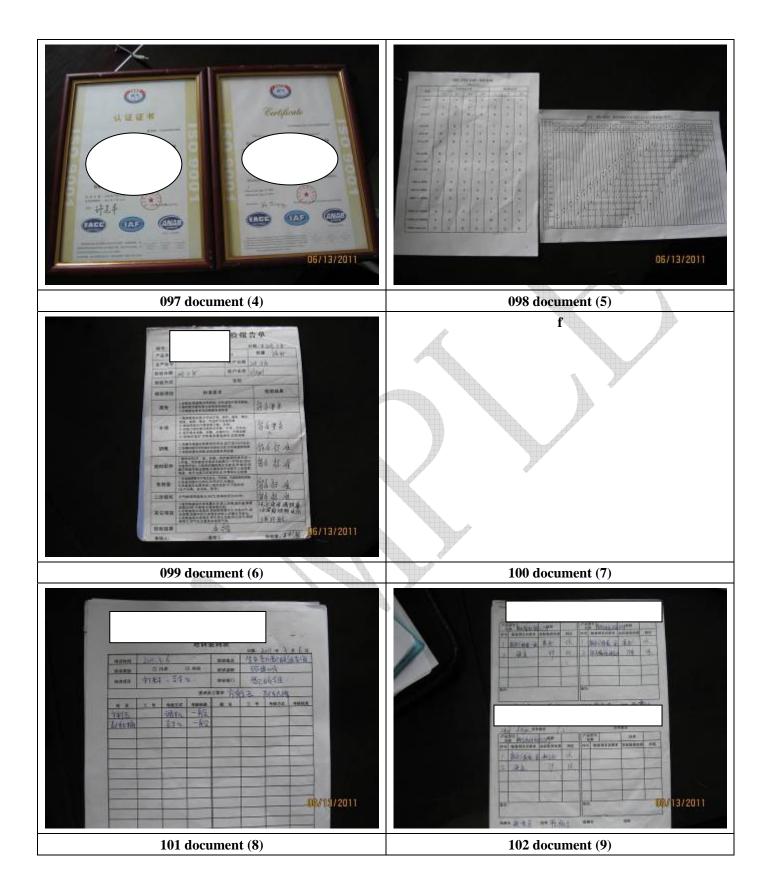


083 finished goods warehouse -capsize stacking

084 finished goods warehouse - capsize stacking







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