

# Audit Report

Global Standard Packaging Materials Issue 6: August 2019

1. Audit summary			
Company name	KUIP MAKE	BRCGS site code	1245436
Site name	KUIP MAKE		
Scope of audit	Forming or selecting and packing of disposable bamboo and wooden tableware (knife, fork, spoon, chopsticks, sign, flower string, plate, flag, steak sign, straw, sandwich, coffee bar, ice cream bar, ice cream spoon, etc.) for food& beverage use		
Scope exclusions	Manufacture of furniture and articles of straw and plaiting materials.		
Justification for exclusion	It is manufactured and stored in segregated and designed areas and can be easily different from the scope, these products can't pose any contamination risk to the products of scope.		
Start date	2022-09-24	Finish date	2022-09-25
Re-audit due date	2023-10-19	Previous audit date	2021-09-26

Additional modules included			
Modules	Result	Scope	Exclusions from Scope
Choose an item	Choose an item		
Choose an item	Choose an item		

2. Audit results			
Audit result	Certificated	Audit Programme	Announced
Audit grade	B	Previous audit grade	B
Certificate issue date	2022-10-07	Certificate expiry date	2023-11-30
Number of non-conformities	Major against SOI of Fundamental	0	
	Critical	0	
	Major	1	
	Minor	6	

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Page 1 of 31	Report No.: NKG2320146	Auditor:	Rupert Rao
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**3. Company details**

Address	No.68, Xingye Road, Yingdong Economic Development Zone, Fuyang City, Anhui Province, 236000		
Country	P. R. China	Telephone	+8613505687687
Commercial representative Name	Yu Yang	Email	yuyang@kuipgroup.com
Technical representative Name	Yu Yang	Email	yuyang@kuipgroup.com

**4. Company profile**

Plant size (square metres)	<10K sq.m	No. of employees	1-50	No. HARA Plans	1-3
Subcontracted activities	No				
Outsourced processes	No				
Other certificates held	ISO9001, FSC, ISO14001				
Regions exported to	North America Europe Asia Choose an item. Choose an item.				
Major changes or auditor observations since last BRCGS audit	No major changes since last audit.				
Company description	<p>The company was established in 2016 and located in No.68, Xingye Road, Yingdong Economic Development Zone, Fuyang City. The areas of production and storage are approx. 800 s.q.m and runs 1 shift/8 hours daily (5 days /week). There is 1 incoming material warehouse, 1 processing room and 1 finished product warehouse.</p> <p>Product: disposable bamboo and wooden tableware (knife, fork, spoon, chopsticks, sign, flower string, plate, flag, steak sign, straw, sandwich, coffee bar, ice cream bar, ice cream spoon, etc.) for food&amp; beverage use. Exclusions: Manufacture of furniture and articles of straw and plaiting materials.</p>				

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Page 2 of 31	Report No.: NKG2320146	Auditor:	Rupert Rao
--------------	------------------------	----------	------------

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4. Company profile	
	Management system: the company has passed the certification of ISO9001, ISO14001 and FSC. The products are provided to Asia, EU and USA.

5. Product and process characteristics	
Manufacturing Categories	06 - Other manufacturing Please select Please select Please select Please select Please select
Products in production at the time of the audit	Wooden fork and knife.

6. Audit duration details			
Total audit duration	12 hours	Duration of production facility inspection	6 hours
Reasons for deviation	None.		
Next audit type selected	Unannounced		

Audit Duration per day			
Audit Day	Date	Start Time	Finish time
1	2022-09-24	13:00	19:00
2	2022-09-25	08:00	14:30

Auditor information		
Auditor number	Auditor Name	Role
20333	Rupert Rao	Lead Auditor
N/A		Please select

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Page 3 of 31	Report No.: NKG2320146	Auditor:	Rupert Rao
--------------	------------------------	----------	------------

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**Present at audit**

Note: the most senior operations manager on site should be listed first and be present at both opening & closing meetings

Name/Job Title	Opening Meeting	Site Inspection	Procedure Review	Closing Meeting
Yu Yang/ Production Manager (MR)	X	X	X	X
Wu Jinxing/ QA Manager	X	X	X	X
Zhang Tingting/ Admin Manager	X	X	X	X
Zhang Xiulan/ Purchase Manager	X	X	X	X

**GFSI Audit History**

Date	Scheme/Standard	Announced/Unannounced
2021-01-30	BRCGS PM issue 6	Announced
2021-09-26	BRCGS PM issue 6	Announced

**Document control**

CB Report number	NKG2320146		
Template Name	P609 Packaging Materials Audit Report Template v11		
Standard Issue	6	Template issue date	2022-02-15
Directory allocation	PackMat	Version	1.0

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Page 4 of 31

Report No.: NKG2320146

Auditor:

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# Non-Conformity Summary Sheet

Major non-conformity against statement of intent of a fundamental requirement				
No.	Clause	Detail	Critical or Major	Re-audit date

Critical				
No.	Clause	Detail		Re-audit date

Major							
No.	Clause	Detail	Correction	Proposed preventive action plan	Root cause analysis	Date reviewed	Reviewed by
1	3.8.2	A documented vulnerability assessment isn't carried out on all raw materials or groups of raw materials to assess the potential risk of substitution.	A documented vulnerability assessment was carried out on all raw materials or groups of raw materials to assess the potential risk of substitution.	To list it in schedule of QA and review the assessment result in management meeting. To train team members. Responsible person: QA Manager.	The team members didn't remember the assessment as requirement. It was not found in internal audit.	2022-09-30	Rupert Rao

Minor							
No.	Clause	Detail	Correction	Proposed preventive action plan	Root cause analysis	Date reviewed	Reviewed by
1	4.2.4	Onsite observed several glass windows of workshop weren't shielded to prevent breakage.	The windows were shielded with films.	To check the condition of glass windows at processing room and warehouse. To train operators to report the conditions when found it wasn't normally. To review the checking records. Responsible person: Production Manager.	The windows weren't shielded due to lack of films, but the films were provided, the MT didn't remember to shield the windows, and production/QA not found it.	2022-09-30	Rupert Rao
2	4.2.7	Onsite observed several lights of workshop weren't worked normally.	The lights were maintained well and worked normally.	To check its conditions and train operators/MT. QA check the result after maintenance. Responsible person: QA.	Operator found it but not report it to MT or chief in time	2022-09-30	Rupert Rao
3	4.9.3.1	The SDS of used ethyl alcohol is not kept on file.	The SDS of ethyl alcohol was kept on file.	To review all SDS of all chemicals. To review it at management meeting. Responsible person: QA	it was missed by chemical room management. QA didn't find this case during regular check.	2022-09-30	Rupert Rao
4	6.2.1	Onsite observed wrist watch was found in workshop.	Training was performed.	To check it and review the checking result by chief monthly.	The operator didn't have enough aware.	2022-09-30	Rupert Rao

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Page 6 of 31

Report No.: NKG2320146

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				Responsible person: QA.	QC also not found during start-up.		
5	6.2.3	Onsite observed the personal telephone was found in workshop.	Training of operator was performed.	To train operators. To check hygiene and safety at start-up To review the checking record at management review. Responsible person: QA Manager.	It wasn't found QA Manager.	2022-09-30	Rupert Rao
6	6.3.5	Onsite observed the signs for hand washing at entrance of workshop weren't provided.	The signs were provided.	To train hygiene operator check handwashing facilities regularly. To update the checking frequency. Responsible person: hygiene operators.	The signs not stamped, QA and hygiene operator not found it.	2022-09-30	Rupert Rao

<b>Comments on non-conformities</b>	
None	

## Additional Modules/Head Office Non-Conformity Summary Sheet

Critical			
No	Clause	Detail	Re-audit date

Major							
No	Clause	Detail	Correction	Proposed preventive action plan	Root cause analysis	Date reviewed	Reviewed by

Minor							
No	Clause	Detail	Correction	Proposed preventive action plan	Root cause analysis	Date reviewed	Reviewed by



## Detailed Section

<b>1.</b>	<b>Senior management commitment</b>
<b>1.1</b>	<b>Senior management commitment and continual improvement</b>
<p>The safety and quality policy are signed by GM on 2020-01-01, Safety and quality policy statement is clearly defined covering legality and product safety requirements. The policy is communicated to all levels of staff by management team.</p> <p>Policy: based on product safety, to obey legislation and requirement of customer, to make customer satisfaction and perfect quality and continuously improve.</p> <p>Summary of targets sets such as:</p> <p>The first test finished product qualified rate over 96%;</p> <p>Customer satisfaction level over 90%;</p> <p>No food safety incident</p> <p>The KPI is communicated through meeting, e-mail, training course, bullet board and we-chart. The monitoring result showed that they had improved all along.</p> <p>For example:</p> <p>The first test finished product qualified rate 97.5%;</p> <p>Customer satisfaction level 92%;</p> <p>No food safety incident</p> <p>GM has committed to provide human resource and financial resource to support BRCGS standard and maintained product safety and quality management system.</p> <p>Company has established action plans to address the activities impact on product safety for development and improvement of the food safety and quality culture. The senior manager who has been involved in the discussion in product safety culture and the activities planned to develop the Food Safety Culture is QA Manager, Production Manager, HR Manager, MT Manager and all other function departments. The main activities include employee quality and safety ability enhancement arrangements and safety &amp; quality communication arrangement. Example for: 1, Investigation: some product safety culture such as safety training/onsite management questions provided to be questionnaire. 2. Based on investigation result, measures including race, discussion, training, PPT display, regularly checking, KPI course are taken. Verification is taken for measure according to BRCGS guidance. The latest evaluation and assessment are performed on 2022-09-29.</p> <p>The company keep up to date with legislation and scientific changes through supplier, government department, BRCGS, customer and internet.</p>	

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Page 9 of 31

Report No.: NKG2320146

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Channels of meeting, e-mail and board notice are implemented according to organization structure chart following employee - manager- (HACCP team leader)-GM.

Example for:

Legislation	Article
2023/2006	GMP
AP 2002-1	Paper
AP2004-2	Cork stoppers and other cork materials and articles intended to come into contact with foodstuffs.
GB4806.8-2016	Wood and paper contact food directly
FDA 21CFR178.3800	Wood preservative
EC 2023/2006	GMP
EU 1935/2004	Materials and articles intended to come into contact with food
EU 1895/2005	Framework Regulation
GB4806.1-2016	Material contact food directly

Current and original copy from BRCGS PM issue 6 is found onsite.

Management on site attend the opening meeting and closing meeting.

Due date is 2022-10-19 and this time is performed on 2022-09-24.

1 MAJOR CAR and 7 MINOR CARs raised in previous audit are corrected, the root causes of any non-conformities against the Standard identified at the previous audit have been effectively addressed to prevent recurrence.

No BRCGS logo used.

**1.2 Management review**

The frequency is once every year. The current management review is conducted on 2022-08-30 charged by GM. Objective is reviewed in meeting. Outputs are 3 suggestions:

- client requirement review
- employee training and evaluation
- facilities maintenance



Monthly meeting about management is also conducted to enables product safety, legality and quality issues to be brought to the attention of senior management and allows for the resolution of issues requiring immediate action.

Example for monthly meeting record of 2022-07-08 for following reviews:

- sample management and communication
- client requirement and email communication
- objectives review

<b>1.3</b>	<b>Organisational structure, responsibilities, and management authority</b>
<p>Quality manual organisational chart and responsibilities are defined, including those with an impact on product safety, legality and quality. Clear organization structure is established covering all business processes.</p> <p>The organisation chart is defined on 2021-01-01. Responsibilities are documented in job description of each position.</p> <p>Documented arrangement in place to cover for the absence of key staff: 2021-01-01.</p> <p>Work instructions are available, communicated and in place for staff that responsible for every key activity related to product safety, legality and quality.</p> <p>Communication channel includes GM- management representative (Team leader) – department-operator and versa.</p>	
<b>Non-applicable clauses</b>	None

<b>2.</b>	<b>Hazard and risk management</b>
<b>2.1</b>	<b>Hazard and risk management team</b>
<p>HACCP is approved on 2021-01-01. 6 HACCP team members are trained with HARA, risk assessment &amp; BRCGS PM requirement in May 2021 and April 2022 by Consult Company. Team members are from different departments. HACCP team leader had over 5 years industry experiences. The internal HACCP training course is performed on 2022-08-27.</p>	
<b>2.2</b>	<b>Hazard analysis and risk assessment</b>
<p>Pre-requisite plans defined in respective procedures, such as cleaning, pest control and foreign bodies control, control procedure and record is kept on file.</p> <p>Relevant information such as scientific literature, historical and known hazard, regulations of destination countries, and HACCP guidance are used as reference for HACCP analysis.</p> <p>The product scopes are clearly identified in HACCP Plan. The potential hazards for all steps are identified and conducted hazard analysis and control measure are established, monitored, verified</p>	

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Page 11 of 31

Report No.: NKG2320146

Auditor:

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and recorded. Product scope: disposable bamboo and wooden tableware for food & beverage use.

Training and meeting reviewed for HA. Consideration such as:

Legislation	Article
2023/2006	GMP
AP 2002-1	Paper
AP2004-2	Cork stoppers and other cork materials and articles intended to come into contact with foodstuffs.
GB4806.8-2016	Wood and paper contact food directly
FDA 21CFR178.3800	Wood preservative
EC 2023/2006	GMP
1935/2004	Materials and articles intended to come into contact with food
1895/2005	Framework Regulation
GB4806.1-2016	Material contact food directly

Product description:

- Product: Wooden/bamboo tableware
- Composition: Wooden/bamboo
- use: food and beverages contact, lower than 168 degrees
- shelf life: 1 year.
- packing: in bags then in cartons or inside woven bags on pallets.

Main processing flow diagram is as following:

Receiving inspection, selecting or forming of bamboo poles or wooden sticks and packing, warehousing and dispatching.

Flow diagram is verified on 2022-08-11.

The hazard analysis is considered with microbiological hazards, chemical contamination, potential for unintended migration of substances from the packaging material, foreign objects, potential problems arising from the use of recycled materials, foreseeable misuse by the consumer, defects critical to consumer safety, hazards that may have an impact on the functional integrity and performance of the final product in use, malicious intervention and fraud. In a totally review:

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Page 12 of 31

Report No.: NKG2320146

Auditor:

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Kind	Hazard
Biological hazard	Pathogen
Chemical hazard	Overall migrations, special migrations, evaporation residue, K4MnO4 consume quantity and heavy metal
Physical hazard	Pest, Metal, wooden pieces
defects critical to consumer safety	Error artwork and information on safety on cartons
Fraud	Material difference
Quality hazard	Width, broken, scratch, broken, sharp, color deviation

Potential hazards are evaluated with likelihood of low to high and severity of low to high then risk grade of low to high was gained through risk matrix, risk grade was defined as low and high after risk assessment, then assessments were conducted based on the following selection and categorization.

After hazard analysis, CQP/CCP (HACCP plan) then planned.

CQP/ CCP	Process	Hazards	CL	Monitoring
CCP1	Raw stick	Chemical migration Mold	1. Raw material shall be from approved suppliers 2. Supplier guarantee shall be in place to show wood sticks are food grade products.	Each batch
CCP2	Hand selecting	Foreign bodies	No foreign bodies, such as metal bodies.	rechecked an hour

The monitoring system, corrective action is established for CCPs and monitored by trained staff. The documentations and records related with product quality and safety are kept in suitable condition.

The review of the hazard and risk management system and prerequisite programme is conducted on 2022-05-23.

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Page 13 of 31

Report No.: NKG2320146

Auditor:

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Non-applicable clauses	None
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**3. Product safety and quality management**

**3.1 Product safety and quality management system**

Manual no KPKJ-SC-2020:  
 Implemented: 2020-01-01  
 Approved: GM.  
 Working methods and practices are documented within FSMS manual. The manual is Chinese version and comprehensive and covered all BRCGS PM requirements.

**3.2 Document control**

Working methods and practices (KPKJ/CX4-01) are documented within product safety and quality control system. The manual is comprehensive and covered all Standard requirements. The controlled document list is established and indicated the latest version number. The document replacing system is implemented. The electronic form is stored with authorised access, control of amendments and password protection, it is backed up to prevent loss.

**3.3 Record keeping**

Quality records control procedure (KPKJ/CX4-02) is established and implemented. Records are maintained in good condition and retrievable, any alterations to records will be authorised and with "Draw a horizontal line and add correct word & signature". The electronic form is stored with authorised access, control of amendments and password protection, it is backed up to prevent loss.

**3.4 Specifications**

Specification list is established for incoming material, process and finished products based on national and EU standard such as:  
 KPKJ-JS-02 incoming products and finished products  
 GB4806.8-2016 Wood and paper contact food directly  
 GB4806.1-2016 Material contact food directly

Raw and finished product specifications are agreed with relevant party through document contract or e-mail confirmation. Manufacturing plan is established and implemented according to prescriptive specifications.  
 Declarations of compliance are reviewed onsite such as recommend letter from supplier and to customer that complied with EU/USA requirement, such as: 2023/2006 for GMP.

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Page 14 of 31	Report No.: NKG2320146	Auditor:	Rupert Rao
---------------	------------------------	----------	------------

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The declaration of compliance contains contents such as: the nature of the materials, confirmation that materials meet relevant legal requirements, no any post-consumer recycled materials, limitations, no allergens and use information.

Company also qualified each material to the third party to confirm to its conformity.

Evidence shows that specifications had been regularly reviewed and updated according to relevant requirement. Review frequency is at least once every 3 years.

Example for knife 3110c during onsite vertical audit:

clear, recipe, reference standard, usage, incoming materials, no allergens, technology, standard GB4806.8-2016 such as size, weight, shelf life and storage conditions, appearance, overall migration limit, heavy metal, packing requirement, labelling, reviewed on 2021-12-26.

**3.5 Internal audits**

KPKJ/CX8-02 internal audit procedure is established. The internal audits must be done at least once a year and frequency based on risk analysis. The latest internal audit is performed this year, 2 minor CARs are raised during internal audit as following:

---audit on 2022-04-20: no any CARs are raised

---audit on 2022-06-27: 1 MINOR CAR is raised

---audit on 2022-08-23: 1 MINOR CARs are raised

Inner auditors are trained of BRCGS PM and HACCP. Internal auditor didn't audit their own works. The responsible person and deadline for corrective action are defined if CAR raised. The performance of the corrective actions will be monitored by QA. (Corrective actions for all non-conformities are verified by internal audit team).

The factory environment combined GMP including hygiene and fabrication is inspected at least monthly, and the inspection and check record is in place. The processing equipment in the workshop is inspected and checked, and the monthly GMP check record of 2022-07-25 is provided.

**3.6 Corrective and preventive action**

The company has established corrective & preventive action procedure to ensure investigation of the root cause of non-conformity will be performed and corrective actions will be taken.

Main steps include:

1. Take corrective actions
2. Analysis and determine the root causes
3. Identify and determine the preventive actions.
4. Carry out preventive actions.
5. Verification of actions.

Any out of control specification would be regarded as non-conformity and reported to QA. The non-conformity would be identified, assessment of consequence, correction and root cause analysis and verification of corrective action effectiveness as well as the trend analysis.

**3.7 Supplier approval and performance monitoring**

A purchasing control procedure KPKJ/CX7-02 is in place for approval and monitoring of all suppliers.





A list of approval suppliers is in place, which is updated regularly according to supplier assessment results. For supplier controls:

1. Questionnaires were used to assess low risk supplier, which were done yearly. The supplier questionnaires included traceability controls, quality controls and safety controls.
  2. On-site audits were done or GFSI certificate for high risk and middle risk suppliers.
- All suppliers must be approved at the first and then entered into the system before they can be used. High risk supplier includes new color master supplier and others are low risk supplier.

Where raw materials were purchased from companies that are not the manufacturer, necessary information to enable the approval of the manufacturer will be obtained.

A plan is in place to carry out ongoing supplier performance review, mainly considering such as:

1. Quality and safety; 2. Complaint handle; 3. On-time delivery; 4. Service Review reports were in place.

The exception control procedure has been documented and will be followed once any exception occurs.

No any new supplier within one year.

Example for assessment records for original supplier during vertical audit:

--Incoming wooden sticks batch JL-043 on 2022-06-07.

--Bamboo/wooden sticks supplier Heilongjiang Linke: evaluation such as license, evaluation report of onsite audit on 2022-07-03, performance score is 92.5%.

--PE bag supplier Taizhou Mingbiao: evaluation such as license, SC, QU, DOC, performance score is 97.0%.

**3.8 | Product authenticity, claims and chain of custody**

The facility establishes the processes to access information on threats to supply chain.

All the control methods are implemented.

**However, MAJOR CAR no.1 is raised, please kindly refer to CAR form.**

**3.9 | Management of subcontracted activities and outsourced processes**

N/A. No subcontracted activities and outsourced processes.

**3.10 | Management of suppliers of services**

A documented service supplier approval policy is defined.

The service servicers and qualified certificates are collected and evaluated its performance annual.

This included: waste service, transportation service, some maintenances, calibration and lab service. The related contracts are kept on files.

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Example for: waste control service contract with contractor Industry Zone EPA and signed on 2021-01-01 and expired to 2024-12-31.

**3.11 Traceability**

The company had in place an identification and traceability control procedure based on paperwork during processing which made the company able to trace materials from raw material source to finished product and vice versa.

The company ensured the traceability of all materials used for its products, such as:

- Batch number for raw material: KP+ A/B+serial no
- Packaging: KP+ A/B+serial no
- Processing semi-finished product: production date
- Finished products: KP+ sale serial no

The traceability system is tested yearly. Last traceability test on 2022-08-07 for signs batch no KP-10621055 quantity 240 ctns to incoming bamboo fork batch no KP-A-024 with quantity check, timescale 1 hour+30 mins.

Onsite auditing sampled:

- Finished knife batch no KP-10621021
- Warehousing: 2022-06-21
- Processing: 2022-06-21
- Incoming wooden knife: batch no JL-043
- Timescale: 1 hour 50 mins
- 100% recovery

**3.12 Complaint handling**

Complaint data with trends and actions taken is kept on file.

Sales department collects complaints from clients, and then deliver it to QA department. The root of cause is analysed by QA. And related person will take actions.

Complaints records will be retained on file, no any complaints are received and dealt. Trend analysis will be conducted to ensure continuously improvement if trend happened.

**3.13 Management of product withdrawals, and incidents and product recalls**

The incident control procedure defines how to control and manage effectively incidents and potential emergency situations that impact food safety, legality or quality such as:

- disruption to key services such as water, power, transport, staff availability and communications
- events such as fire, wind, flood or natural disaster
- malicious contamination or sabotage
- failure of or attacks against, digital cyber-security

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- COVID-19 with control such as responsible access, temperature measuring, registration, segregation

Last fire emergency test dated 2022-05-28 with records retained.

No actual recall by far.

The product recall procedure is tested annually. It was defined in the procedure that in the event of a product recall, SGS shall be informed within three working days of the decision to issue a recall.

Mock recall report initialled by the factory on 2022-08-07 for signs batch no KP-10621055 quantity 240 ctns, designed quality problem, mock recall includes trace test, communication plan, recovery calculation (recovery 100%). The scenario considered by the recall team included a test of the decision making of the team and how they decided if the scenario would result in a recall or withdrawal.

Non-applicable clauses

3.9: No subcontracted activities and outsourced processes.

#### 4. Site Standards

##### 4.1 External standards

There are 4 buildings in plant:

1 building for office

1 building (3 layers): the second floor for workshop and warehouse, others for other products.

2 building (1 layer): warehouse for other products

The boundary walls with 1 guard room at entrance of plant.

The building of the factory is maintained with investments regularly planned.

The grounds and parking lots of the exterior are graded to prevent standing water.

The building is kept in normal condition to prevent accesses of contaminations.

No local activities around the factory that would risk product contamination.

##### 4.2 Building fabric and interiors: raw materials handling, preparation, processing, packing and storage areas

Walls: cement and/or with paint or steel boards

Floor: cement and/ or with paint.

Entrance: air shower, hand washing facilities, changing room with hand washing facilities

On site verification, the fabrication of the buildings and facilities such as the wall and floor are suitable for the intended purpose.

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Page 18 of 31

Report No.: NKG2320146

Auditor:

Rupert Rao

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Walls, floors, drainages, doors, ceiling and overheads are regularly maintained.

No mould growth on the wall.

In the workshop verification, floors are designed to meet the requirement of the process. And drainage is designed and maintained to minimise risk of product contamination.

No stagnant water is observed.

Existing glass windows fitted with shatter checking regularly.

The UV lights aren't protected but those are checked, and the check record is provided.

Exhaust fans are in place and routinely checked.

**However, MINOR CAR no.1 and MINOR no.2 are raised, please kindly refer to CAR form.**

**4.3 Utilities**

Potable water: city potable water. The water is used for plant cleaning.

Testing report of potable water: issued on 2021-08-11, indicators such as Formaldehyde, arsenic, cadmium, lead, mercury, fluoride, chloroform, carbon tetrachloride, color, smell and taste, total radioactivity and Escherichia coli, standard refer to GB5749-2006.

No ice or vapour used.

**4.4 Site security and product defence**

Food defence plan SA01 is established and evaluated yearly and last dated on 2022-04-09. Last in-house training dated on 2022-09-06. Enclosed site with 24-hour security staffs.

Production areas and warehouses are restricted areas and monitored via CCTV, visitors are not permitted enter except accompanying person presence.

Gatekeeper is responsible to control entrance of employees, contractors and visitors and persons would not be permitted to enter the factory without authorization.

**4.5 Layout, product flow and segregation**

There is effective segregation in place to minimise the risk of product contamination, the plan of the site which designates areas where product is at different levels of risk from contamination is defined in PRP:

- Raw material inspection zone- low risk area
- processing - high risk area for workshop
- Finished product storage zone – low risk area



Detailed plan of the site including access points for personnel and travel routes, location of staff facilities and routes to the facilities from places of work, production process flow, routes for the removal of waste is in place.

Working space and storage are sufficient to enable operations to be carried out properly under safe hygienic conditions.

**4.6 | Equipment**

Most equipment contact surfaces are made of stainless steel. Engineers aware of the requirement. Equipment have been specified before purchase, and then tested and commissioned prior to use.

Equipment is positioned normally to facilitate cleaning and service. Equipment is positioned to facilitate cleaning and service.

**4.7 | Maintenance**

In-house engineers reported to maintenance supervisor who operated documented maintenance plan.

Total 1 maintenance employee exists in the factory. The device and equipment will be maintained as designed maintenance schedule, and the maintenance record is reviewed.

If temporary repairs are necessary, safety of product will be protected.

Tools and parts into workshop are count and collected at beginning and finishing, relevant records are in place.

No major breakdowns in last 12 months.

Food grade lubricant with NSF H1 registration no 124623 is used.

Documented hygiene inspection on start-up completed by production managers.

Maintenance room is separated from production area and is tidy during the audit.

**4.8 | Housekeeping and cleaning**

Housekeeping and hygiene systems defined cleaning objects, cleaning methods, frequency, used chemicals, operator and safety requirement and detailed as:

- Cleaning is done by appointed operator
- After finishing work, each batch and changeover
- Ethyl alcohol is used in the product contact surface as the disinfectant
- Verification of the cleaning and disinfection by visually check and testing is demonstrated: daily cleaning visually check by QC

SGS United Kingdom Limited 217-221 London Road, Camberley, GU15 3EY, Tel 01276 697854 E-mail globalbrc@sgs.com

Page 20 of 31

Report No.: NKG2320146

Auditor:

Rupert Rao

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Company will identify improvement point from result of verification if non-conformity happened. The trend map is kept on file. No non-conformity is found based on history of trends.

During audit on site, ceiling, the equipment, tools, the surface of the contact food, wall in the cleaning manner. Training records are in place.

Based on risk and client requirement, the microbiological environmental monitoring programme is established, assessment report is performed based on risk such as disinfection before use at clients, high temperature during extrusion, workshop used, history and microbe testing for finished product regularly, hygiene control condition, cleaning plan and facilities, awareness and client requirement. The assessment is conducted on 2021-12-03. the result: testing indicators such as TPC for hand, M/C, environment and protective clothing, testing frequency is yearly, the latest test is performed on 2022-06-27.

**4.9 Product contamination control**

**4.9.1 Glass, brittle plastics, ceramics, and similar materials control**

Glass and brittle material control procedure is developed.

The procedures for handling glass, brittle or hard plastic, ceramic or other materials include the requirement to inspect on a frequency monthly.

The list of the glass and brittle material is available; the inspection records are seen and specify the responsible persons as well as the result and the date.

Example for checking record between April 2022 and May 2022.

**4.9.2 Sharps and metal control**

Documented policy for the control of the use of sharp metal implements including scissors, knives is in place and there is daily inspection record for damage and the investigation of any lost items. Staples and wooden tools are not allowed in the open product area.

**4.9.3 Chemical and biological control**

Documented chemical control procedure with a reference of SSOP5 is in place, the approved chemical list and relative MSDS are in place, for example, MSDS and testing report of alcohol is reviewed. Cleaning chemicals stored in a locked room, restricted access.

Chemical list includes: such as hand washing soft soap, 75% alcohol and lubricant oil.

Risk and risk analysis for microbiological hazard is conducted in risk management risk analysis sheet. It is used to identify biological risk and allergen and control these risks such as:

No allergens based on investigation in lubricant.

**However, MINOIR CAR no.3 is raised, please kindly refer to CAR form.**

**4.10 Waste and waste disposal**



Disposal is normally managed. External waste collection container is cleaned in time. External waste is stored in sealed container. Collection containers are available with label and cover. Plant clean external waste collection containers regularly. Unsafe products or substandard trademarked materials are handled to be destroyed by own staffs at first with control record and then confirm with contractor.

**4.11 | Pest management**

Documented preventive pest control programme is maintained covering all areas of the site to minimize pest infestation.

undertaken by the qualified PCO, the staffs are adequately trained by CDC, keep up to date with pesticide legislation, and dedicated locked facilities are used for the storage of pesticides.

procedure defined in the event of infestation, or evidence of pest activity, immediate action needs to be taken to identify at-risk products and to minimise the risk of product contamination and any potentially affected products should be subject to the non-conforming product procedure. No any such events are happened.

frequency is once every two months for November to April, twice monthly for other months.

target organisms including: rodent, fly, cockroach, culex

device include trap, pest killer, glue board and bait station

non-toxic bait is used

pest control plan, maps and visit reports (frequency is at least monthly)

during onsite audit the inspection records between March 2021 and June 2021 are sampled for viewing

during onsite audit no pest infestation happened

no any major instances since the previous audit

An in-depth, documented pest control survey is conducted yearly, and onsite inspection survey dated on 2022-07-30.

The relative trending analysis of the pest control quarterly.

Employee pest control aware training is performed on 2022-08-22.

**Non-applicable clauses**

4.2.6: no elevated walkways are adjacent to or pass over production lines  
 4.3.2: not directly contact with product  
 4.4.3: No external storage tanks, silos and any intake pipes with an external opening

**5. | Product and process control**

SGS United Kingdom Limited 217-221 London Road, Camberley, GU15 3EY, Tel 01276 697854 E-mail globalbrc@sgs.com

Page 22 of 31

Report No.: NKG2320146

Auditor:

Rupert Rao

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**5.1 | Product development**

Product formulation is established. The manufacturing processes have been trialled and product extensively tested to ensure compliance with agreed customer specifications. All new products and changes to product formulation, packaging or methods of processing are formally approved by the risk management team members, and it is checked, the reports for new products are in place.

The critical-use parameters are identified and defined such as max/min use/storage temperature, process data, use of recycled materials, size, color, thickness etc. all data defined to conduct test in sampling plan.

The safety and legal issue are confirmed by clients. In the system, the R&D is responsible for the informing the recipe/process defined in the trials to the clients via the sales/ customer service staffs.

The trail samples are kept in place.

A documented procedure is in be in place to address the transfer of customer specifications or requirements to the site's own systems. It is charged by R&D and guidance with hazard and risk management team.

**5.2 | Graphic design and artwork control**

Graphic and artwork control procedure including artwork control.  
 Graphic design was responsible for customer and provide the artwork to factory.  
 The formal acceptance and approval of final product concepts and artworks by the specifier are in place, it is validated that the agreed product quality and artwork standards at start up and regularly.  
 Production is verified with correct specification, correct samples and artwork version or agreed master prior to use and signed with responsibility.  
 Customer-approved reference material including e-mail is stored and segregated / controlled well.

**5.3 | Packaging print control**

N/A. No packaging print activities.

**5.4 | Process control**

SOP operating procedure has established.

The following critical manufacturing process control points are defined after review:

Main process	Main control parameters
Selecting	Defects less than 1%, to find out the foreign bodies, each pcs

**SGS United Kingdom Limited** 217-221 London Road, Camberley, GU15 3EY, Tel 01276 697854 E-mail [globalbrc@sgs.com](mailto:globalbrc@sgs.com)

Page 23 of 31	Report No.: NKG2320146	Auditor:	Rupert Rao
---------------	------------------------	----------	------------

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Operating procedure is implemented.

Quality check is performed as the requirement of designed plan, quality performance and SOP of each process control point with sampling plan according to GB2828.

Checking is conducted at start up, processing regularly and at the edge of stopping. Clearance record is established for stopping and turnover.

**5.5 Calibration and control of measuring and monitoring devices**

Calibration for the testing and measuring device control programme SMP08:2020 is developed and covering following:

checking frequency

checking methods

trained staff to carry out the checks when the device shall be internal calibrated

Operators are aware of the procedures to be undertaken.

Measuring and monitoring devices has been calibrated by government department according to national standard and calibration certificates have been maintained in time in plant.

Example for:

Calliper: certificate no L2202100070684, type 0-150mm, serial no 111903823, issue 2022-02-10

Steel rule: certificate no L2202110070676, type 5m, issue 2022-02-11

Electronic scale: certificate no M2202100070682, type BSA-224S, serial no 111303402, issue 2022-02-10

**5.6 Product inspection, testing and measuring**

Lab inspection rules are in place for all materials and environment.

The company has an in-house laboratory to undertake analyses or qualified inspection by subcontracted labs to confirm product safety, legality and quality, using appropriate procedures, facilities and standards.

Main raw materials checking items such as:

Incoming material: label, moisture, colour, size, foreign bodies and COA: once/ each batch;

Semi-finished product: appearance, colour, size, weight, strength, dropping test and leakage test: once/ batch;





Finished product: colour, size, weight, appearance, strength test and chemical migration test: once/batch;

The trend analysis is performed yearly. Company will identify improvement point from result of verification if non-conformity happened. The trend map is kept on file.

Test final products refer relevant regulations by government lab and subcontracted labs. Outside labs test indicators such as overall migration, heavy metal and extraction.

Example for testing report of wooden knife: testing report no WUHRH220801-002-971, issued on 2022-08-01 according to EC REG NO 1935/2004, specific migration of formaldehyde, Pentachlorophenol (PCP) and heavy metal.

**5.7 | Control of non-conforming product**

KPKJ/CX8-05 Non-conformed product control procedure is defined and implemented.

Clear process well understood by staffs that are interviewed during the audit. Special container in special area for non-conforming products are provided and stored separately.

For incoming material: rejection in time, responsibility is QA receiver;

For semi-finished product: production operator must be isolated and label non-conforming product, QA responsible for assessment and evaluation;

For finished product: test finished products and isolate/evaluate the non-conformity, QA responsible for evaluation and handling and making a loss.

Procedure defines how to handle and conduct potential trend analysis.

The statistic of non-conformity product is conducted by QA operator, any potential trend is performed in corrective action report based on each quality levels such as size, appearance, colour etc.

The potential trends are reviewed in management meeting and corrective action will be followed in next circle.

**5.8 | Incoming goods**

Receiving procedure is established for each incoming material. Purchase order/ deliver sheet, COA, label and packing condition is checked at first according to receiving standard, then material sampling to check appearance, size and testing in lab based on receiving standard, material will be rejected if non-conformity happened. Raw material and packaging material inspection and test procedure is established and implemented.

The received materials are verified by authorized person such as QA prior receiving.

Materials then are stored in incoming materials warehouse and labelled and used by FIFO rule.

**SGS United Kingdom Limited** 217-221 London Road, Camberley, GU15 3EY, Tel 01276 697854 E-mail [globalbrc@sgs.com](mailto:globalbrc@sgs.com)

Page 25 of 31

Report No.: NKG2320146

Auditor:

Rupert Rao

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**5.9 | Storage of all materials and intermediate and finished products**

All materials are separately stored in the storage.

All the materials are required to store on the pallets and away from floor. The stock rotation is based on FIFO system.

Chemicals are handled in such a way that risk to product safety, quality and legality is minimized.

Material intended for recycling is segregated and labelled.

Normal temperature for storage only.

**5.10 | Dispatch and transport**

Document transportation control procedure are in place and during the audit, the loading area is clean, the condition is followed the transportation requirements.

The warehouse employee will inspect the container before loading. The inspection item: cleanness, pest activity and dilapidation. The container is not passed until inspection results is OK.

Raw material and packaging transport arranged by suppliers.

Finished products are shipped with the third-party company. All facilities used for the transportation of product, movement around the site, and dispatch of finished product are suitable for the purpose, maintained in good repair and in a hygienic condition.

<b>Non-applicable clauses</b>	5.2.3/5.2.4: No packaging print activities 5.3: No packaging print activities 5.6.3/5.6.6/5.6.9: no in-line inspection equipment
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**6. | Personnel**

**6.1 | Training and competence: raw materials handling, preparation, processing, packing and storage areas**

Training records for all personnel, including temporary personnel and contractors are in place.

Training plan is in place, the training items are detailed including testing, operation guidance, chemical control, safety control, CCP/HACCP, ISO9001, GMP and BRCGS PM.

Training methods include meeting room course and onsite training. For CCP training, each CCP point is trained at first in meeting course with questionnaire and then onsite operation training. The training result is evaluated by trainer based on meeting room course and onsite training. Example for the latest HACCP/CCP training course is performed on 2022-08-27.

Evaluation for staff is conducted through site operation, antitheses, examination or discussion. Employee can't conduct work if training not passed.

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Page 26 of 31	Report No.: NKG2320146	Auditor:	Rupert Rao
---------------	------------------------	----------	------------

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The competencies of its staff are reviewed at least once a year, and related training is performed based on evaluation result.

**6.2 | Personal hygiene: raw materials handling, preparation, processing, packing and storage areas**

Documented personal hygiene control procedure GMP is developed and implemented. Hand cleaning is performed at a reasonable frequency and the effectiveness of hygiene procedure is checked periodically.

No jewellery, rings are worn by the employees and managements. And it is checked and monitored by the appointed employee before into the workshop.

Documented processes and SOP are in place to control use and storage of personal medicines, personal medicines are not permitted to take into workshop, medicine are kept in office for storage. Training of staff is conducted.

**However, MINOR CAR no.4 and MINOR CAR no.5 are raised, please kindly refer to CAR form.**

**6.3 | Staff facilities**

Sufficient hand-washing facilities are provided at the entrance of workshops.

Hand washing station provided at each processing workshops entrances;

- Taps are hand-free
- Air drying device
- Disinfection is realized via 75% ethyl alcohol
- Hand washing policy is defined and posted

In the processing zone and packing zone, the dedicated protective clothing is used, and the pointed employee checked the hygiene policy

Toilets are adequately segregated and do not open directly into storage

Men and woman toilets are adequately segregated and do not open directly into storage.

Personal items include outdoor clothing are stored in small closet in changing- room, no food is permitted in production and store area.

Designated smoking room located outside the production area and storage area, and no risk from smoking wastes to product.

**However, MINOIR CAR no.6 is raised, please kindly refer to CAR form.**

**6.4 | Medical screening**

The medical screening procedure GMP is in place for all employees or visit who will work in or visiting area where product safety could be compromised.

The health check for relative employee is carried out at least once per year and the licenses are retained on file.

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Page 27 of 31

Report No.: NKG2320146

Auditor:

Rupert Rao

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When employees suffer disease and return to work after recovery, reporting system is established to monitor and confirm this condition.

Documented SOP in GMP is established for employees, contractors and visitors may be suffering from or have been in contact with infectious disease. Personal will be investigated and provided with health / health report and then can enter workshop and storage areas. QU for visitors, outer contractor is performed before they enter into workshop and warehouse.

**6.5 Protective clothing**

Each employee has at least 2 work uniforms including caps, coats, pants and work shoes according to different risk grade.

Protective clothing is different form in different risk area and position. The changing room to workshop based on risk area is performed.

Hands washed and sanitised before entering production area.

Completed protective clothing should be put on before entering workshop, visitors and contractors. Protective clothing must be changed in changing room before to toilet and use of canteen and smoking areas outside workshop.

Protective clothing is cleaned by company laundry by operators. Instructions are trained to operators. Clean bag for pack is defined, clean of protective clothing is checked during receiving with checking record.

Disposable glove is provided to employee and changed every shift or needed.

Mask is disposable and changed every day.

Non-applicable clauses

6.4.3: it can contact food directly.

**Requirements for traded products**

**7.1 Approval and performance monitoring of manufacturers/packers of traded packaging products**

N/A. No traded products.

**7.2 Specifications**

N/A. No traded products.

**7.3 Product inspection and laboratory testing**

N/A. No traded products.

**7.4 Product legality**

SGS United Kingdom Limited 217-221 London Road, Camberley, GU15 3EY, Tel 01276 697854 E-mail globalbrc@sgs.com

Page 28 of 31

Report No.: NKG2320146

Auditor:

Rupert Rao

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N/A. No traded products.	
7.5	Traceability
N/A. No traded products.	
Non-applicable clauses	7.1/7.2/7.3/7.4/7.5: No traded products.

Additional Module: Plastic Pellet Loss Prevention	
10.1.1	Senior management commitment and control improvement
N/A. No module.	
10.2.2	Hazard analysis and risk assessment
N/A. No module.	
10.3.5	Internal audits
N/A. No module.	
10.3.6	Corrective and preventive action
N/A. No module.	
10.3.13	Management of incidents
N/A. No module.	
10.4.2	Building fabric and interiors: raw materials handling, preparation, processing, packing and storage areas
N/A. No module.	
10.4.4	Site security
N/A. No module.	
10.4.5	Layout
N/A. No module.	
10.4.8	Housekeeping and cleaning
N/A. No module.	
10.4.10	Waste and waste disposal
N/A. No module.	
10.5.8	Incoming goods
N/A. No module.	
10.6.1	Personnel: training and competence

SGS United Kingdom Limited 217-221 London Road, Camberley, GU15 3EY, Tel 01276 697854 E-mail globalbrc@sgs.com

Page 30 of 31

Report No.: NKG2320146

Auditor:

Rupert Rao

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N/A. No module.	
Non-applicable clauses	10.1.1~ 10.6.1: No module.