Audit Summary

Facility Name:	Shanghai Chuangshi Industry (Group) Co., Ltd.	**Project ID:**	248596
Site Address(es):	No. 388, Zhangliantang Road, Qingpu District, Shanghai 201700, China		
Contact Person:	Jamie Zhang	**Contact Email:**	jamie@shchuangshi.com.cn
Contact Phone:	+86-21-31166566	**No. Shifts:**	1
No. Employees:	330	**Audit Language:**	Chinese
Lead Auditor:	Sidney Gong	**Audit Team:**	N/A
Audit Dates:	8/15-17/2017	**Total # Audit Days:**	3
Audit Program:	Retail Certification Program	**Audit Activity:**	Re-certification Audit
Scope of Audit:	Current Good Manufacturing Practices as defined by the FDA's 21 CFR Part 820 related to the manufacturing, packaging and warehousing of Hot and Cold Packs.		

Audit Summary

This Audit Summary provides a preliminary description of the outcome from the audit carried out at the organization listed at the top of this page. Details relating to the date, time and duration of the audit were confirmed with the organization through an audit itinerary received prior to commencement. An independent evaluation of systems and processes used to control operations and production was then carried out relating to the listed scope of the audit. A summary of findings appears below, along with significant notes of interest on the next page of this summary.

As with any inspection / audit process, sampling may not reveal nonconformities that could be found by the same, other UL Registrar auditors, or outside second or third-party audit bodies on subsequent visits. Findings are subject to review and verification by UL Registrar LLC, and therefore remain provisional until confirmed through issuance of the final audit report.

CAPA Effectiveness Verification

Previous CAPAs verified as effective and closed at this visit:

CAPA IDs: CA-001-2016-CSI, CA-002-2016-CSI, CA-003-2016-CSI

Previous CAPAs not verified as effective, and are therefore reissued from this visit:

CAPA IDs: N/A

Summary of Findings from This Visit

Audit Scope / CFR Reference	Outcome	Critical	Major	Minor
21 CFR Part 820 Medical Devices	Pass	0	0	3
(Please select)	(Please select)			
(Please select)	(Please select)			

I have reviewed the scope statement noted above with the auditee and verify its accuracy.

I agree that the above client information and audit scope are correct as listed above. All non-conformities have been fully explained.

Respectfully Submitted (Signed Electronically):

Signed for / and On Behalf of the Facility:

Lead Auditor:	Sidney Gong	Signature:	He Yan
Date:	8/17/2017	Date:	17/8/2017

Audit Summary

Review of Marks and Badges

Certificate Marks/Badges are not owned by the auditee and not available onsite.

Audit Summary Comments

Auditor notes here, including: use of Marks and Badges, and/or changes for next audit are listed below:

(Please write notes here)

Review of Recent US-FDA Investigation

No FDA investigation occurred within the last 2 years.

(Please write notes here)

OPENING MEETING
Introduce UL Registrar LLC and the Audit Team.
Thank the factory for hosting the audit.
Circulate Audit Opening Meeting attendance sheet.
Confirm the Regulatory Audit Standard.
Explain the GMP Audit Process. If applicable, explain the certification requirements for the program to which you are auditing (RCP, NBCP, etc.).
Explain that UL Registrar “Seeks Conformance not Nonconformance”.
Stress the need for openness on part of auditee as well as the auditors.
Explain UL R confidentiality – any additional non-disclosure required? *If so, contact UL R for guidance on whether or not to sign the form.*
Explain that Auditing is a sampling process.
Explain UL R's CAPA classifications, Major and Minor and Critical.
Explain and clarify the process for communicating nonconformances, including significant findings during the audit.
Confirm the Audit itinerary and Scope of audit. Alert the UL R Office of any significant changes (additional buildings/scope changes).
Inquire about any specific Health or Safety precautions / use of Personal Protective Equipment.
Confirm a private place to work / phone / photocopier / printer (if applicable).
Confirm Lunch Arrangements.
Invite questions relating to the audit process or audit program.
Confirm time of daily debriefing (if multi-day) and Final Closing Meeting.
CLOSING MEETING
Circulate Closing Meeting attendance record.
Reconfirm Contact Person and Addresses - record any changes.
Read CAPAs and explain CAPA follow-up - timeframes and response email are listed on the CAR form.
Explain the 'Summary of Findings from This Visit' on the Audit Summary, including the Audit Outcome. Ensure Outcome is marked properly with regards to program requirements.
Explain again that a Major (and/or Critical, if applicable) CAPA and/or a marginal audit score may require a follow-up audit.
Explain the Reporting Process, and that results are provisional until confirmed by technical and QA review.
Explain that the audit represents a point in time and other auditors may assess the same areas with different results.
Describe Disputes and Appeals Process - any complaints, disputes or appeals can be sent to the CAPA email on the form.
Thank the factory for Hosting the audit. Ensure you have all signatures needed on the Audit Summary and CAPA form.
Auditor and Auditee Sign Auditor Ethics Certification form.

Audit Summary

Auditor confirms that he/she has covered the above topics in the opening/closing meetings.

Sidney Gong

Ethics Certification

The undersigned certifies that they have not been an employee of the auditee, nor has the undersigned participated in the development of the auditee's Quality System, or conducted internal auditing of said company within the last two (2) years.
Additionally, the undersigned is fully aware of the ethical, impartiality and conflict of interest requirements of UL Registrar LLC.
The undersigned certifies full compliance with the signing and dating of this document.
(Signed electronically.)

Auditor Signature: Sidney Gong **Date:** 8/17/2017

Auditor Signature: _____ **Date:** _____

Auditor Signature: _____ **Date:** _____

Customer Verification:

To the best of our knowledge, the affidavit relating to independence by the above named auditor(s) is true and correct.

Auditee Signature: He Yan **Date:** 17/8/2017

Title: QA Manager

Attendance Record

Name:	Position:	Open: 8/15/2017	Close: 8/17/2017
Sidney Gong	UL Auditor	x	x
He Yan	Quality Manager	x	x
Qian Weibin	HR Manager	x	x
Mei Feng	Purchase Manager	x	x
Hu Zhijun	Production Manager	x	x
