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445 Sixth Street, NW | Grand Rapids, MI 49504
toll free: 833.4OLIVER
www.oliverhcp.com

Dear valued customer,

Enclosed is Oliver Healthcare Packaging Company's (Olivers') standard response to quality surveys and questionnaires. Due to the large volume of similar requests from our customers, it is Olivers' policy to provide this response as a way to efficiently address these important issues and answer your questions. In addition, please find attached our Quality Manual, ISO 13485 Certificate and Documented Procedures for the QMS. Oliver has achieved ISO 13485 registration at all locations.

As part of our compliance efforts, we have implemented:

- Quality Manual (structured around ISO 13485)
- Documented Operating and Administrative Procedures
- Quality Process (i.e. CAPA, Managing Nonconformances)
- Internal Environmental, Health and Safety (EH&S) and Quality Audits
- Product Tracking (computerized lot control and traceability)
- Certificates of Conformance

Oliver has comprehensive policies and procedures in place to ensure our facilities comply with applicable standards and regulatory requirements, are operating safely and efficiently, and that our employees are effectively trained.

Oliver is committed to patient safety and product quality. This commitment is driven by top management and shared by all Oliver employees. We're proud of the fact that our quality program meets the stringent standards of medical device and pharmaceutical manufacturers worldwide.

The enclosed documents and our organization's structure, positions Oliver to meet the regulatory and quality requirements of our customers. Please contact the Customer Care Representative or Regional Manager for your account if you have any further questions about Oliver. We appreciate your interest in our organization and look forward to our business activities.

Respectfully,

DocuSigned by Rodney Yee
Rodney Yee | I approve this document 3/4/2024 | 2:56 PM EST
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Rodney Yee
Director of QA/RA

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General Questions

Company Name and Overview:
Oliver Healthcare Packaging Company

The company was founded in 1890 and started as Oliver Machinery. In 1981, Oliver Machinery changed its name to Oliver Products and then changed again to Oliver Medical in 2005. In 2009, Oliver Medical acquired Tolas and became Oliver-Tolas Healthcare Packaging. In 2016 Oliver acquired Mangar Industries and in early 2017 changed the company name to Oliver Healthcare Packaging. In 2018 Oliver acquired CleanCut Technologies, LLC in Anaheim, CA. In 2020 Oliver officially became Oliver Healthcare Packaging Company. Oliver is classified as a large business.

	Grand Rapids - USA	Hamilton - USA	Feasterville - USA	New Britain - USA	Anaheim – USA	Venray - The Netherlands	Suzhou - China
Address	445 Sixth St NW, Grand Rapids, MI 49504 USA (Headquarters)	3840 Symmes Rd, Hamilton, OH 45015 USA	905Pennsylvania Blvd., Feasterville, PA 19053 USA	97 Britain Drive New Britain, PA 18901 USA	1145 N. Ocean Circle Anaheim, CA 92806 USA	Spurkt 1, NL-5804 AR VENRAY, The Netherlands	No.27 Chunyao Road, Caohu Street, Xiangcheng District Suzhou, China
Telephone	616.456.7711	513.860.6880	215.322.7900	215.230.0300	714.864.3500	+31 478 517 560	+86 512 6917 1258
Fax	616.456.5820	513.860.6888	215.322.9034	215.230.0133	714.864.3595	+31 478 630 840	N/A
Square footage	≈ 166,000	≈ 38,400	≈ 134,500	≈ 21,400	≈ 70,000	≈ 41,000	≈68,490
Number of employees	≈ 320	≈ 50	≈ 260	≈ 200	≈ 210	≈ 100	≈59
Tax ID	38-2363773	38-2363773	38-2363773	38-2363773	38-2363773	NL 810371911	42-130-6311
Dunn and Bradstreet number	07-829-8780	07-829-8780	07-829-8780	07-829-8780	07-829-8780	40-671-2013	07-829-8780
NAICS numbers	326112	326112	326112	326112	326112	NA	NA

Products and Services Supplied:
Medical device and pharmaceutical packaging for sterile applications

The following individuals represent the primary company, customer and product interface functions:
Michael Benevento, President and CEO
Anne Curwin, President Americas
Doug Kramer, CFO
Russell Douglas, Vice President of Global Operations
Thomas Jeziorski, Vice President of Strategic Accounts
Steven Pepe, Vice President of Global Marketing
Kevin Zacharias, Technical Director
Jody Beeck, Director of Sales Operations
George Gramas, Director of Operations
Rodney Yee, Director of Quality Assurance and Regulatory Affairs
Ryan Wasson, Director of Global Procurement

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Trade and Customer references for Suzhou facility:

Company	*Phone*	*Contact*
Corning Incorporated Life Sciences	0512-63196534	Xiong Bing
BD Medical Devices Co., Ltd. Suzhou	0512-67616787	Steven Jin
Changshu Yushan Protection Products CO., Ltd.	0512-26522392	Luo Surong

ISO Certifications:

ISO 13485 Certifications: all manufacturing sites are currently certified to ISO 13485:2016 – QMS Registration certificates for all facilities are available online (www.oliverhcp.com) or upon request by contacting your Customer Care Representative.

Exclusions:

- Hamilton, Ohio: Design and development (ISO 13485; 7.3)
- Feasterville, Pennsylvania: Design and development (ISO 13485; 7.3)
- Grand Rapids, Michigan: Design and development (ISO 13485; 7.3)
- New Britain, Pennsylvania: Design and development (ISO 13485; 7.3)
- Venray, Netherlands: Design and development (ISO 13485; 7.3)
- Suzhou, China: Design and development (EN ISO 13485; 7.3)
- Anaheim, California: Some Design and Development Activities, see section 7.3 in Oliver Quality Manual

Cleanroom Certifications:

- ISO 14644-1 certified ISO 7 cleanroom, Grand Rapids facility; Sheeter 2/Auto Pack Cell Room, 2 Zone Coat Rooms
- ISO 14644-1 certified ISO 5 laminar flow hoods, Grand Rapids facility
- ISO 14644-1 certified ISO 8 cleanroom, Grand Rapids facility; Die Cut Lid Room; Pouch 7 Room
- ISO 14644-1 certified ISO 7 cleanroom, Feasterville facility; Hand Assembly Area
- ISO 14644-1 certified ISO 8 cleanroom, Feasterville facility; Sheetfed Area; Pouch Area
- ISO 14644-1 certified ISO 8 cleanroom, Feasterville facility; 2 Slitting Areas
- ISO 14644-1 certified ISO 8 cleanroom, Anaheim facility; Production Area
- ISO 14644-1 certified ISO 7 cleanroom, Anaheim facility; Final Packout Area
- ISO 14644-1 certified ISO 8 cleanroom, Venray facility
- ISO 14644-1 certified ISO 7 cleanroom, Venray facility
- ISO 14644-1 certified ISO 7 cleanroom, Suzhou facility (Also meet YY/T0033:2000 class 10000 requirement).

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Quality Policy:

Our highest priority is to exceed customer expectations through exemplary service and the supply of high quality products to ensure patient safety.

We are committed to maintaining the effectiveness of the quality management system through the review of quality objectives and compliance with regulatory requirements.

Quality Management System:

1) Is there an established, documented, implemented and maintained quality system?	Quality Manual 4.1
2) Are processes identified, their interactions determined, and methods of control implemented, monitored, measured and analyzed?	Quality Manual 4.1
3) Is there a quality manual, quality policy and documented procedures?	Quality Manual 4.2.1 & 4.2.2
4) Is there an established process for the control of documents?	Quality Manual 4.2.4
5) Is there an established process for the control of records?	Quality Manual 4.2.5

Management Responsibility:

1) Is there evidence of top management commitment, defined authority and responsibility for maintaining an effective quality system?	Quality Manual 5.1
2) Has customer focus (requirements) been determined, met and measured?	Quality Manual 5.2
3) Is the quality policy periodically reviewed for suitability?	Quality Manual 5.3
4) Have quality objectives been determined?	Quality Manual 5.4.1
5) Has quality management system planning been established to meet requirements and objectives?	Quality Manual 5.4.2
6) Has a Management Representative been appointed, and associated responsibilities and authorities defined?	Quality Manual 5.5.2
7) Is there an established internal communication process?	Quality Manual 5.5.3
8) Are Management Reviews/Quality Meetings conducted to report on the status and effectiveness of the quality system? (established inputs and outputs)	Quality Manual 5.6

Resource Management:

1) Have provisions for resource needs been determined and provided to maintain the effectiveness of the quality system and enhance customer satisfaction?	Quality Manual 6.1

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2) Are the education, training, skill and experience requirements of personnel established?	Quality Manual 6.2
3) Is employee competence, awareness and training determined, evaluated, documented and maintained?	Quality Manual 6.2
4) Is there a process to determine, provide and maintain the needed infrastructure?	Quality Manual 6.3
5) Is a suitable work environment identified and managed?	Quality Manual 6.4

Product Realization:

1) Is there a process in place to plan, develop, measure, record and validate product realization?	Quality Manual 7.1
2) How do you communicate supplier specification and/or internal process changes?	Quality Manual 7.2.2
3) Is there a process in place to determine, review and communicate customer requirements related to the products?	Quality Manual 7.2.2 & 7.2.3
4) What is the process used by Oliver Healthcare Packaging to plan and control the design and development of product?	Quality Manual 7.3.1
5) How does the organization determine the Design and Development Inputs?	Quality Manual 7.3.3
6) How can design and development outputs be verified against the inputs?	Quality Manual 7.3.4
7) At what stages of design and development do you perform reviews to evaluate if the results meet requirements?	Quality Manual 7.3.5
8) What verification activities are performed to ensure that the design and development outputs have met the input requirements?	Quality Manual 7.3.6
9) What design and development validation activities are performed to ensure that the product is capable of meeting the requirements for the intended use?	Quality Manual 7.3.7
10) Is there a process in place to ensure product conforms to purchasing requirements?	Quality Manual 7.4.1
11) Is supplier selection, approval, evaluation and re-evaluation established and records maintained?	Quality Manual 7.4.1
12) Are purchases restricted to approved suppliers and products?	Purchasing product is controlled and restricted to those suppliers and products listed in the ERP System & Approved Supplier List.
13) Is there a process in place to ensure products meet requirements?	Quality Manual 7.4.3
14) Have inspection and/or other methods to ensure product conformity been identified and implemented?	Quality Manual 7.4.3
15) Is there an implemented plan for production to be carried out in controlled conditions regarding product information, work instructions, suitable equipment and monitoring and measuring devices, as applicable?	Quality Manual 7.5.1

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16) Do you have any production or service processes where the resulting output cannot be verified by subsequent monitoring or measurement?	Quality Manual 7.5.6
17) Is there appropriate identification and traceability of products?	Quality Manual 7.5.8 Identification and 7.5.9 Traceability is maintained electronically through the ERP system
18) Is there control of customer property while under our care?	Quality Manual 7.5.10
19) Is product preservation implemented including identification, handling, packaging, storage and protection?	Quality Manual 7.5.11
20) Have appropriate monitoring and measuring devices been determined, identified, implemented, and verified or calibrated, as required, to ensure product conformity?	Quality Manual 7.6

Measurement, Analysis and Improvement:

1) Is there an implemented plan to monitor, measure, analyze and improve processes needed to demonstrate product conformity and the effectiveness of the quality management system?	Quality Manual 8.1
2) Is customer satisfaction and/or perception monitored and measured?	Quality Manual 8.2.1
3) How is supplier performance monitored?	Quality Manual 8.4
4) Do you perform external audits of raw material and service suppliers?	Yes, as needed
5) Are internal audits conducted at planned intervals documenting the criteria; reporting results; identifying non-conformances with follow-up activities; and maintaining records?	Quality Manual 8.2.4
6) Is there a process in place to monitor and measure processes?	Quality Manual 8.2.5
7) Is there a process in place to monitor and measure products?	Quality Manual 8.2.6
8) Are there documented and implemented methods to control nonconforming product? (identification, segregation, investigation, disposition)	Quality Manual 8.3.1
9) Is there a process in place to demonstrate the analysis of data relating to customer satisfaction, product requirement conformance, process and product improvements and supplier performance?	Quality Manual 8.4
10) Are there continual improvement efforts done through the use of the quality policy, quality objectives, audit results, analysis of data, corrective/preventive actions and management reviews?	Quality Manual 8.5.1
11) Is there a documented system in place to record, evaluate, identify the root cause, determine a corrective and/or	Quality Manual 8.5.2 & 8.5.3

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preventive action, create action plans, and follow-up on the effectiveness of the action plans relating to non-conforming situations?	

Good Manufacturing Practices:

1) Are employees trained on GMP upon hire?	Yes, as required for job function in applicable facilities.
2) Are device and pharmaceutical grade materials stored in a manner consistent with customer's guidelines in order to preserve the integrity of the product?	Yes
3) Is a system in place where the distribution of each lot of device or pharmaceutical grade product can be readily determined to facilitate its recall if necessary?	Yes, through traceability of our ERP operating system.

Maintenance/Preventive Maintenance:

1) Is there a Preventative Maintenance Program in place?	Quality Manual 6.3
2) Are there methods in place to verify site compliance to the PM program?	Yes, internal audits
3) Are PM non-compliance issues addressed?	Yes, corrective actions are put in place; potential remedial actions are assessed and reviewed by the Regional Operations and Quality Managers.

Pest Control:

1) Is there a formal documented Pest Management Program in place for product storage areas to prevent product adulteration from insects, rodents and other pests?	Yes, all areas.
2) Is the Pest Control Program maintained by a facility certified pesticide applicator or licensed pest control operator?	Yes
3) Is a master list of application areas and/or pest control devices maintained on file?	Yes

Housekeeping/Cleaning:

1) Is a cleaning schedule established for product storage areas?	Yes

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2) Where applicable for product handling/repackaging areas, are documented cleaning procedures using approved cleaning agents established to prevent contamination of product, equipment and packaging materials?	Yes

Revision History

Revision	Section Changed	Change Made	Effective Date
14	Revision History	Added Revision History Section Changed NAICS Number from 322220 to 326112 for GR, HM, FV, NB & AN. Amended ISO 7 Cleanrooms for GR and the ISO 5 Laminar Hoods.	11-2021
15	Page 1 Page 2 Page 5 & 7	Add ‘‘Documented Procedures for the QMS” Add “Oliver is classified as a large business” Update table, names & titles. Change Visual to ERP	03-2024