



Solutions

CERTIFICATE OF REGISTRATION

Astoria-Pacific, Inc.

15130 SE 82nd Drive
PO Box 830
Clackamas, Oregon 97015 UNITED STATES

Facility ID: F001388

UL Medical Regulatory Services of UL LLC® (UL Solutions) issues this certificate to the Firm named above, after auditing the Firm's quality management system and finding it in conformance per the defined scope with respect to:

ISO 13485:2016

EN ISO 13485:2016

with additional regulatory requirements listed on final page of this certificate.

The design and manufacture of in vitro diagnostic reagents, test kits, and controls for use in the detection and screening of neonatal metabolic disorders. The design, manufacture, installation and service of microplate processing instrumentation used in the detection and screening of neonatal metabolic disorders.

With additional locations listed on Addendum: 1



Authorized by

Paul Hilgeman
Senior Business Manager - Medical
CMIT – Medical Regulatory



Check Certificate Status:
[here](#)

File Number	A16452	Cycle Start Date	July 13, 2022
Certificate Number	1423.230713	Effective Date	July 13, 2023
Initial Issue Date	May 29, 2018	Expiry Date	July 12, 2024

This quality system registration is included in UL's Directory of Registered Firms and applies to the provision of goods and/or services as specified in the scope of registration from the address(es) shown above. By issuance of this certificate the firm represents that it will maintain its registration in accordance with the applicable requirements. This certificate is not transferable and remains the property of UL Medical and Regulatory Services of UL LLC® (UL Solutions). Certificates may be verified by visiting the Online Certifications Directory on UL.com.



**UL Medical and Regulatory
Services UL, LLC is an
MDSAP Recognized
Auditing Organization**

UL Solutions
333 Pfingsten Road
Northbrook, IL 60062-2096 USA



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Addendum 1

1-1

Facility ID: **F001388**

Astoria-Pacific, Inc.

**15130 SE 82nd Dr., PO Box 830
Clackamas, Oregon 97015 UNITED STATES**

Performing: Design/Engineering, QMS, Final QC, Purchasing Shipping/Receiving/Instrument production

1-2

Facility ID: **F001388**

Astoria-Pacific, Inc.

**15140 SE 82nd Dr., Suite 250
Clackamas, Oregon 97015 UNITED STATES**

Performing: Reagent production, In process QC, Kitting, Storage

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Additional Regulatory Requirements

Canada:

- Medical Devices Regulations – Part 1- SOR 98/282

United States:

- 21 CFR 820
- 21 CFR 803
- 21 CFR 806
- 21 CFR 807 – Subparts A to D
- 21 CFR 821 (where applicable)

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