

Certificate of Registration

Certificate number

1423.240713

File number

A16452

Initial issue date

2018-05-29

Cycle start date

2022-07-13

Effective date

2024-07-13

Expiry date

2025-07-12

**Astoria-Pacific, Inc.**

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

UL LLC, UL Solutions medical and regulatory services issues this certificate to the Firm named above, after assessing the Firm's quality system and finding it in conformance per the defined scope with respect to:

**ISO 13485:2016
EN ISO 13485:2016/A11:2021**

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.

Certificate with Addendum(s) totals 3 pages.

Authorized by:

A handwritten signature in black ink, appearing to read 'P. Daysh'.

Paul Daysh
Operations manager – Medical Regulatory



Check certificate status: [here](#)

This quality system registration is included in UL's Product IQ directory and applies to the provision of goods and/or services as specified in the scope of registration from the address(es) shown. By issuance of this certificate, the firm represents that it will maintain its registration in accordance with the applicable requirements. This certificate is not transferrable and remains the property of UL Solutions.

**UL LLC, UL Solutions medical regulatory services
is an MDSAP Recognized Auditing Organization**

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

Addendum 1

Site	Company Name	Location	Performing
1-1	Astoria-Pacific, Inc.	15130 SE 82nd Dr. PO Box 830 Clackamas Oregon 97015 UNITED STATES Facility ID: F001388	Design/Engineering, QMS, Final QC, Purchasing Shipping/Receiving/Instrument production
1-2	Astoria-Pacific, Inc.	15140 SE 82nd Dr. Suite 250 Clackamas Oregon 97015 UNITED STATES Facility ID: F001388	Reagent production, In process QC, Kitting, Storage

Additional Regulatory Requirements

Astoria-Pacific, Inc.

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

Facility ID: F001388

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)