Certificate of Registration

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A16452

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Cycle start date

2025-07-13

Effective date

2025-07-13

Expiry date 2028-07-12





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, manufacturing, and distribution of in vitro diagnostic reagents, test kits, and controls for use in the detection and screening of neonatal metabolic disorders. The design, manufacturing, installation, and service of microplate processing instrumentation used in the detection and screening of neonatal metabolic disorders. Contract manufacturing of reagents, test kits, and controls for in vitro diagnostic use. Contract manufacturing of 3D printed non-implantable, non-active medical devices and medical device components for general laboratory and in vitro diagnostic use.

Certificate with Addendum(s) totals 2 pages.

Authorized by:



Paul Daysh Operations manager – Medical Regulatory

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 333 Pfingsten Road Northbrook, IL 60062-2096 USA



Addendum 1

| Site | Company Name | Location | Performing |
|------|-----------------------|---------------------|-------------------------------|
| 1-1 | Astoria-Pacific, Inc. | 15130 SE 82nd Drive | Design, QMS, Final QC, |
| | | PO Box 830 | Purchasing, Shipping, |
| | | Clackamas | Receiving, Instrument |
| | | Oregon | production |
| | | 97015 | |
| | | UNITED STATES | |
| 1-2 | Astoria-Pacific, Inc. | 15140 SE 82nd Drive | Reagent production, In |
| | | Suite 250 | process QC, Kitting, Storage, |
| | | Clackamas | Contract IVD reagent |
| | | Oregon | manufacturing |
| | | 97015 | |
| | | UNITED STATES | |
| 1-3 | Astoria-Pacific, Inc | 15140 SE 82nd Drive | Engineering, Design, |
| | | Suite 270 | Contract 3D printing |
| | | Clackamas | |
| | | Oregon | |
| | | 97015 | |
| | | UNITED STATES | |

