



CERTIFICATE OF REGISTRATION

Orion Diagnostica Oy

Koivu-Mankkaan tie 6 B, P.O. Box 83
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UL LLC®(UL) issues this certificate to the Firm named above, after assessing the Firm's quality system and finding it in compliance with:

ISO 13485:2016

EN ISO 13485:2016

The design and development, manufacture and servicing of in-vitro diagnostic test kits, reagents and analyzers/software used in the diagnosis and management of cancer, immune status, disease status, autoimmune status, cardiac makers, protein metabolism, transmissible agents and pregnancy testing including point of care and near patient use.

Design, development and manufacture of hygiene tests.

Sales of in-vitro diagnostic test kits and reagents used in the diagnosis and management of several different statuses including point of care and near patient use.

Authorized by



Michael J. Windler, P.E.

Manager of Global Regulatory Service

Distinguished Member of the Technical Staff
Life and Health Sciences, UL LLC



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Status: [here](#)

File Number	A13894	Cycle Start	June 26, 2018
Certificate Number	1691.190109	Effective Date	January 9, 2019
Initial Issue Date	June 26, 2018	Expiry Date	June 23, 2020

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 LLC.



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