

Orion Diagnostica Oy

P.O. Box 83, 02101
Koivu-Mankkaantie 6B,
02200 Espoo, Finland

With manufacturing locations at:
Tengströminkatu 6-8
20360 Turku, Finland

Kiviharjuntie 11
90220 Oulu, Finland



Underwriters Laboratories Inc.® (UL) issues this certificate to the Firm named above, after assessing the Firm's quality system and finding it in compliance with

ISO 9001:2008

EN ISO 9001:2008; ANSI/ISO/ASQ Q9001-2008; CAN/CSA-ISO 9001-08

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 markers, protein metabolism, endocrine disorders, blood analytes, blood components, coagulation, transmissible agents, sexually transmissible agents, fertility testing and pregnancy testing including point of care and near patient use.

The purchase for resale of in-vitro diagnostic test kits and reagents used in the diagnosis and management of cancer, genetic testing, immune status, disease status, autoimmune status, drugs of abuse, cardiac markers, protein metabolism, endocrine disorders, blood analytes, blood components, blood gases, coagulation, transmissible agents, sexually transmissible agents, fertility testing, pregnancy testing and for immunological typing and therapeutic drug monitoring including point of care and near patient use.

Design, development and manufacture of hygiene tests.

The location at Tengströminkatu 6-8, 20360 Turku, Finland performs manufacture of in vitro diagnostic reagents.

The location at Kiviharjuntie 11, 90220 Oulu, Finland performs design, development and manufacture of in vitro diagnostic reagents.

File Number: A13894
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Expiry Date: June 23, 2014



Anil N. Patel
General Manager, UL Health Sciences



Further clarifications regarding the scope of this certificate and the applicability of ISO 9001:2008 requirements may be obtained by consulting the organization.

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 Underwriters Laboratories Inc.

Certificate of Registration

Underwriters Laboratories Inc.
333 Pfingsten Road
Northbrook, IL 60062 USA