

ISO 9001

Orion Diagnostica Oy

P.O. Box 83, 02101 Espoo, Finland

Koivu-Mankkaantie 6B,

02200 Espoo, Finland

Manufacturing site located:

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Finland

Manufacturing site located:

Koivu-Mankkaantie 6 B

02200 Espoo,

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 9001:2000

EN ISO 9001:2000; BS EN ISO 9001:2000; ANSI/AAMI/ISO 13485:2003

ISO 13485:2003

EN ISO 13485:2003; CAN/CSA 13485:2003 and EN ISO 13485:2003

for the following scope of registration

2835 (US) : In Vitro and In Vivo Diagnostic Substances

The product development, manufacture, marketing, and sales of in vitro diagnostic reagents and test systems for basic microbiology, for hormone and marker assays, for protein assays and for infectious disease diagnostics, as well as sales of external third party products at the premises in Espoo.

Further clarifications regarding the scope of this certificate and the applicability of ISO 9001:2000 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. ®.

File Number: A13894

Volume: 1

Original Certification Date: June 24, 2005

ISO 9001:2000 Issue Date: June 24, 2005

ISO 13485:2003 Issue Date: June 24, 2005

Revision Date: April 08, 2008

Recertification Date: June 24, 2008

Renewal Date: June 23, 2011



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