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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 13485:2003

EN ISO 13485:2003, CAN/CSA ISO 13485:2003 and ANSI/AAMI/ISO 13485:2003

for the following scope of registration

2835 (US) : In Vitro and Vivo Diagnostic Substances

3826 (US) : Laboratory Analytical Instruments

The design, development, manufacture, service, and distribution of in vitro diagnostic medical devices and in vitro diagnostic analyzers used in the diagnosis of cancer, disease status, drugs of abuse, cardiac markers, fertility testing and pregnancy testing including home use and near patient in vitro diagnostic devices. The servicing of in vitro diagnostic analyzers used in the diagnosis of cancer, disease status, drugs of abuse, pregnancy testing and cardiac markers.

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.®, 333 Pfingsten Road, Northbrook IL 60062, USA.

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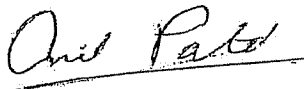
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