ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

CERTIFICATE

No. QS6 123606 0002 Rev. 00

Certificate Holder: **PATHNSITU BIOTECHNOLOGIES PVT LTD**
PS Heights, Plot A-28/1/11B/B
Road no 15/2, IDA Nacharam
Hyderabad, Telangana 500076
INDIA

Certification Mark:

Scope of Certificate: **Design and Development, Manufacturing, and Distribution of In-Vitro Diagnostic Reagents and Reagent Products for Immunohistochemistry**

Design and Development, Manufacturing, Distribution, Installation and Servicing of In-Vitro Diagnostic Instruments for Immunohistochemistry and Histology Applications

Standard(s): **ISO 13485:2016**

Regulatory Authority(ies): **Health Canada. See attached for listing of specific regulatory requirements.**

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. For details and certificate validity see:
www.tuvsud.com/ps-cert?q=cert:QS6 123606 0002 Rev. 00
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID: **F008071**
Report No.: **201530002090**
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(Renee Walker)
Director, US Certification Body, MHS

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C E R T I F I C A T E

No. QS6 123606 0002 Rev. 00

Regulatory Requirements: **Audit/Certification Criteria**

Canada
- Medical Device Regulations – Part 1- SOR 98/282

Facility(ies): **PATHNSITU BIOTECHNOLOGIES PVT LTD**
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Nacharam, Hyderabad, Telangana 500076, INDIA

Facility Scopes: Design and Development, Manufacturing, and Distribution of In-Vitro Diagnostic Reagents and Reagent Products for Immunohistochemistry

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