



## Certificate of Registration

OUALITY MANAGEMENT SYSTEM - ISO 13485:2003 & EN ISO 13485:2012

This is to certify that:

Omega Dx (Asia) Pvt. Ltd.

4th Floor, BTS-2, Chryslis Enclave Bloc No.2, Plot No. 2A, International Biotech

Park, Rajiv Gandhi Infotech Park Hinjewadi Phase-II, Pune 411 057

Maĥarashtra

India

Holds Certificate No:

MD 661700

and operates a Quality Management System which complies with the requirements of ISO 13485:2003 & EN ISO 13485:2012 for the following scope:

The Design, Manufacture and Supply of Immuno-Diagnostic Products and Reagents.

For and on behalf of BSI:

Frank Lee, EMEA Compliance & Risk Director

Original Registration Date: 15/12/2016 Latest Revision Date: 14/02/2017 Effective Date: 15/12/2016 Expiry Date: 28/02/2019

Page: 1 of 2

bsi.



...making excellence a habit."

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract. An electronic certificate can be authenticated **online**.

Printed copies can be validated at www.bsi-global.com/ClientDirectory or telephone +91 11 2692 9000.

Further clarifications regarding the scope of this certificate and the applicability of EN ISO 13485:2012 requirements may be obtained by consulting the organization.

This certificate is valid only if provided original copies are in complete set.

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000 BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK. A Member of the BSI Group of Companies.

Certificate No: MD 661700

Location Registered Activities

Omega Dx (Asia) Pvt. Ltd.

4th Floor, BTS-2, Chryslis Enclave

Bloc No. 2, Plot No. 2A, International Biotech

Park, Rajiv Gandhi Infotech Park Hinjewadi Phase-II, Pune 411 057

Maharashtra

India

Omega Dx (Asia) Pvt. Ltd.

Kanakia Spaces, Western Edge 1

Off W.E. Highway

Boriwali (E)

Mumbai 400 066

Maharashtra

India

Omega Dx (Asia) Pvt. Ltd.

C/o Bhanu Ice and Cold Storage Pvt. Ltd.

D202, 6C, TTC Industrial Area

MIDC, Turbhe

Navi Mumbai 400 703

Maharashtra

India

registered recivities

Functions/ Activities are Design & Manufacture.

Distribution.

Sales & Marketing.

Effective Date: 15/12/2016

Original Registration Date: 15/12/2016 Effective Date: 15/12/2016

Latest Revision Date: 14/02/2017 Expiry Date: 28/02/2019

Page: 2 of 2

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract. An electronic certificate can be authenticated <u>online</u>.

Printed copies can be validated at www.bsi-global.com/ClientDirectory or telephone +91 11 2692 9000.

Further clarifications regarding the scope of this certificate and the applicability of EN ISO 13485:2012 requirements may be obtained by consulting the organization. This certificate is valid only if provided original copies are in complete set.