

assessors of quality

Certificate No. MD-QMS/91/R/I/2289/f

This is to certify that

Qualpro Diagnostics - A Division of Tulip Diagnostics (P) Ltd.

Corporate Office: Gitanjali, Tulip Block, Dr. Antonio Do Rego Bagh, Alto Santacruz, Bambolim Complex P.O., Goa - 403 202, India (a list of certified workplaces is contained in Annexure which is inseparable part of this Certificate)

has been found to conform to the requirements of Medical Devices - Quality Management System Standard

ISO 13485:2016

This certificate is valid for the following scope:

Design, Development, Manufacture and Distribution of IVD Medical Devices based on Lateral Flow Immunochromatography, Enzyme Linked Immunoassay (ELISA) and Chemiluminescence Immunoassay (CLIA) technologies used in the diagnosis of Infectious Diseases.

Technical Area/s (Ref. IAF MD9):

A.1.4

Initial Certification : 29/05/2015
Re-certification : 27/05/2021
Valid until : 28/05/2024
Modified on : 18/06/2022

(Replaces withdrawn Certificate No. MD-QMS/91/R/I/2289/e issued on 27th May, 2021)









Authorised Signatory

The authenticity of this document may be re-affirmed by writing to <u>certification@zenith-worldwide.com</u>. Lack of fulfillment of conditions as set out in the Certification Agreement may render this certificate invalid. Any alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of law.



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Annexure to Certificate No. MD-QMS/91/R/I/2289/f

Issued to the Company

Qualpro Diagnostics - A Division of Tulip Diagnostics (P) Ltd.

<u>Scope of Certification</u>: Design, Development, Manufacture and Distribution of IVD Medical Devices based on Lateral Flow Immunochromatography, Enzyme Linked Immunoassay (ELISA) and Chemiluminescence Immunoassay (CLIA) technologies used in the diagnosis of Infectious Diseases.

Workplaces and Scope of Activities:

Corporate Office : Gitanjali, Tulip Block, Dr. Antonio Do Rego Bagh, Alto Santacruz,

Bambolim Complex P.O., Goa - 403 202, India

Scope of Activities : Management, Human Resource, Marketing & Sales

Site-1 : Plot No. 88/89, Phase IIC, Verna Industrial Estate, Verna, Goa - 403 722, India

Scope of Activities: Human Resource, Design & Development, Production, Quality Control, Quality

Assurance & Raw Material Stores

Site-2 : Plot Nos. S-124 & S-125, Phase III B, Verna Industrial Estate, Verna, Salcete,

South Goa – 403 722, India

Scope of Activities : Purchase

Scope of Activities : Finished Goods Stores & Dispatch

 Initial Certification
 : 29/05/2015

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