

BSCIC

Certificate

MEDICAL DEVICE-QUALITY MANAGEMENT SYSTEM

This is to certify that:

SELOI HEALTH CARE PVT. LTD.

UNIT NO. 401 & 402, 4TH FLOOR, SHRI SAI CORPORATE PARK LAXMI NAGAR, OPP. NEW LINK ROAD, GOREGAON WEST MUMBAI - 400 104, MAHARASHTRA, INDIA

Hereby granted the Certificate Number:

BN21071/20458

Subsequent to the Assessment of the organization, it has been found to be operating a Medical Device-Quality Management System which complies with the requirements of

ISO 13485:2016

For the following scope:

Design, Manufacture & Supply of In-Vitro Diagnostic Kits Rapid Test Viz (hCG Pregnancy Test Kit, Dengue IgG/ IgM Test Kit, Typhoid IgG/ IgM Test Kit, LH (Ovulation) Test Kit, Covid 19 Ag Test Kit, Malaria Pf/Pv Ag Test Kit, Malaria Pf/Pan Ag Test Kit, Dengue NS1 Ag Test Kit, Dengue Combo (NS1 + IgG/IgM)

Test Kit, HIV 1/2 Triline Test Kit, Syphilis Ah Test Kit, HCV Ab Test Kit, HBsAg Test Kit,

Chikungunya Test Kit, Vitamin D Test Kit, Viral Transport Media (VTM) Kit,

Troponin I (Cardiac Marker) Test Kit, Malaria Pf Ag Test Kit
Technical Area: Reagents and Reagent Products, Calibrators and Control Materials for:
Immunochemistry (Immunology), A.1.4.2 IVD Medical Devices other than Specified Above, A.1.4.9

Originally 29-Sep-2022 1st Surveillance Due on: 28-Sep-2023

Registered:

Issue Date: 29-Sep-2022 2nd Surveillance Due on: 28-Sep-2024

Expiry Date: 28-Sep-2025

Sanjay Seth Managing Director

BSCIC CERTIFICATIONS PVT.LTD.

(In case if Surveillance Audit is not allowed to be conducted; this Certificate shall be Suspended/Withdrawn).

Please Re-validate this certificate's status at www.bsc-icc.com at REGISTRATION STATUS.

This Certificate of Registration is granted subject to relevant provisions of the BSCIC Certifications PVT. LTD. Contract Terms & Scheme for Registration Form 8018 (Latest Version). Please see 8018 at our website www.bsc-icc.com.

The certificate of Registration remains the property of BSCIC Certifications Pvt. Ltd. and shall be returned immediately upon request. BSCIC Headquarters: &work, 1st Floor, 5B/15A, Crown Plaza Mall, Faridabad - 121 007, Haryana, India.

Version No. 1







