CERTIFICATE OF COMPLIANCE



INTERNATIONAL CERTIFICATION SERVICES PVT. LTD.

This is to certify that the

MEDICAL DEVICES - QUALITY MANAGEMENT SYSTEM of

MARK ENTERPRISES

Shed No 1, Plot No-93/2, Street No. 17, Satpur MIDC, Nashik - 422007, Maharashtra, India.

has been assessed and registered as complying with the requirements of the following International Standard:

ISO 13485: 2016

The Medical Devices - Quality Management System applicable to:

Scope: Design, Development, Manufacturing, Installation And Servicing Of Medical Cold Chain And Blood Bank Equipments Such As; For Refrigerators - Refrigerated Centrifuge, Blood Bank Refrigerator, Ice Lined Refrigerator, Ice Lined Blood Storage Refrigerator, Active Vaccine Transporter/Active Cold Box, Laboratory Refrigerator, Walk-In Cooler/Cold Room, Refrigerated Vaccine Storage Truck, Vaccine Storage Van, Cryoprecipitate Bath/Refrigerated Water Bath, Platelet Incubator With Agitator, Incubator, BOD (Bio-Oxygen Demand) Incubator. For Freezers - Solar Direct Drive Vaccine Refrigerator And Freezer, Deep Freezer (-10°C To -40°C), Ultra Low Temperature Deep Freezer (-20°C To - 86°C), Walk-In-Freezer. For Allied -Programmable Remote Temperature And Event Monitoring System, Blood Donor Chair, Table, ICU (Intensive Care Unit)/Operating Bed, Non-Refrigerated Centrifuge, Blood Bag Tube Sealer (Di Electric Tube Sealer), Plasma Expresser (Automatic/Manual), Blood Collection Monitor (Biomixer), Laminar Air Flow, Plasma Thawing Bath, Autoclave, And Related Accessories.

> Registration No. Registered Date

Issue Date

: RQMD91/11497

: 01st August, 2023 : 16th August, 2023

: 31st July, 2026 **Expiry Date**







QMS 009

Invalid After 27/06/2024 Unless

Invalid After 27/06/2025 Unless

Director (Technical) International Certification Services Pvt. Ltd. Accredited by National Accreditation Board For Certification Bodies, India.

Validity of this certificate is based on periodic audits of the management system defined by the above scope and is contingent upon prompt, written notification of significant changes to the management system and/or its components thereof shall be immediately communicated to ICS.

Further clarifications regarding the scope of this certificate and the applicability of ISO 13485:2016 requirements may be obtained at www.icsasian.com/ www.icspl.org