CERTIFICATE OF COMPLIANCE



INTERNATIONAL CERTIFICATION SERVICES PVT. LTD.

This is to certify that the MEDICAL DEVICES - QUALITY MANAGEMENT SYSTEM of

HIPPOCRAT BIOMEDICAL LLP

Registered Address: 1402, New MHADA Complex, Cluster 4, L-15 Opp. Surya Shopping Centre, Penkar Pada Mira Road (EAST) Thane-401107, Maharashtra, India.

Factory Address: Gala No.C/10, Unit No. DV01/1347, Ganesh Industrial Estate, Devdal, S.No.43, H.No.1/2/B, Near Sagar Hotel, Bhiwandi Road, Village-Kaman, Tehsil-Vasai, Dist.Palghar - 401208, 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: Manufacturing, Packaging Labeling Sale and Distribution of Medical Device Non-Sterile Regular Dialysis Fluid like bicarbonate concentrate, A and B concentrate like Haemodialysis Bicarbonate Solutions, and Haemodialysis Bicarbonate Powder Assembly of Haemodialysis Bicarbonate Mixer Manufacturing, Packaging Labeling Sale and Distribution of Disinfectant for Haemodialysis Medical Device like Peracetic Acid and Hydrogen Peroxide Based Cold sterilant, Citric Acid Based Hot Disinfectant and Sodium Hypochlorite Solution.

Registration No.

: RQMD91/11988

Registered Date

: 23rd October, 2024

Issue Date

: 25th October, 2024

Expiry Date

: 22nd October, 2027







RED
Invalid After
16/10/2025
Unless
Hologram
Pasted

GREEN Invalid After 16/10/2026 Unless Hologram Pasted



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