



Letter No.: ICS/CO/CER/L/24-25/16821
Date: 25th October, 2024

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

Dear Sir,

Subject: Certification of Quality Management System for Medical Devices

We are pleased to inform you that the recommendation for registration of the Quality Management System for Medical Devices system in accordance with ISO 13485:2016 of your organization has now been accepted.

We on behalf of International Certifications Services wish to thank you in having trust and confidence in ICS Certification Services and extending your co-operations during the audits.

Please find enclosed herewith the following documents for your information and records.

- a) Certificate of Compliance (RQMD91/11988)
- b) Trade Mark License Agreement (TMLA)
- c) Initial Audit Report (already submitted earlier)
- d) Mark of Prestige, Annexure VA of CM, Issue 1, rev 5. Please refer CM5 and TMLA for usage of logo.
- e) CM-5, Certification of Management System requirements (refer: www.icspl.org)
- f) CM-16, Complaints & Appeals (refer: www.icspl.org)

CM-5 gives the description of the certification services and provides updated information on changes in certification requirements. Please note that surveillance audits will be conducted as agreed during the validity of the certificate in order to verify that management system maintained effectively and improved on continual basis. The surveillance audit will include the following elements as a minimum.

- a) Internal Quality Audit
- b) Management review meeting
- c) Corrective & Preventive Actions



- d) Management responsibility and Changes in Organization (if any)
- e) Customer Complaints
- f) Process System and Improvement.
- g) Continual Improvement
- h) Sample of other elements of applicable ISO applicable standards.
- i) To ensure that the International Certifications Services and Accreditation body logo is used as per guidelines given in the TMLA. You are requested to go through the guidelines for the use of the Quality Mark of Prestige and strictly adhere to the requirements.

We would like to observe that your Organization complies with requirements and follows the guidelines of International Certification Services and the Accreditation Body for NABCB with regard to maintaining of the Management System and proper usage of Logo as per the Annexure VA. We also request you to keep us informed immediately upon any changes in your Organization, Certification Scope and System and associated procedures, system and process.

Please note that original certificate is affixed with ICS Hologram that is the ICS main Hologram as per shown validity marked on the certificate. Another 2 nos. ICS holograms will be affixed upon successful completion of the Surveillance Audits by the ICS Lead Auditor / Team Leader that will ensure continuity of the certificate.

We assure you our prompt and value added services every time we audit your organization.

With thanks and best regards,



Sumeet Kataria
Director (Technical)
For International Certification Services Pvt. Ltd.

YOUR TRUSTED PARTNER IN MANAGEMENT SYSTEMS