ISO 13485:2016

Certificate of Registration

This is to Certify that
Medical Device Quality Management System of

AMBALSOFT INFOTECH PRIVATE LIMITED

32/11, PITCHU STREET, MYLAPORE, CHENNAI – 600004,
TAMILNADU, INDIA.

has been assessed and found to conform to the requirements of

ISO 13485:2016

for the following scope :

DESIGN, DEVELOPMENT, MANUFACTURE, SALES, INSTALLATION AND SERVICING OF MEDICAL DEVICE SOFTWARE: CAPTUREITPRO - MEDICAL IMAGING AND REPORTING SOFTWARE, COLPOITPRO - COLPOSCOPY IMAGING AND REPORTING SOFTWARE, OPTOITPRO - OPHTHALMOLOGY IMAGING AND REPORTING SOFWARE, CEMR - CLINIC MANAGEMENT AND HOSPITAL INFORMATION SYSTEM WITH MOBILE VIEWER, CAPTUREONE – PICTURE ARCHIVING AND COMMUNICATION SYSTEM (PACS) AND DICOM WORKSTATION SOFTWARE AND CAPTUREINSIGHTAI – AI-BASED POLYP DETECTION SYSTEM

Certificate No	: **26EMSD27**		
Initial Registration Date	: 07/11/2020	Issuance Date	: 05/11/2026
Date of Expiry	: 04/11/2029		
1st Surv. Due	: 05/10/2027	2nd Surv. Due	: 05/10/2028

Director

EGAC Accredited
MDQMS Certification
CAB # 012226

MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT IAF

(Scan to Verify)

Assurance Quality Certification LLC
Head Office: Sharjah Media City, SHAMS, Sharjah, UAE. e-mail: info@aqcworld.com,
Key Location: A-60, Sector - 2, Noida, Uttar Pradesh, 201301, India.

**Validity of the Certificate is subject to successful completion of surveillance audit on or before of due date. (in case surveillance audit is not allowed to be conducted, this certificate shall be suspended/withdrawal).*
Certificate Verification: Please Re-check the validity of certificate at http://www.aqcworld.com/activeclients.aspx or www.aqcworld.com at Active Clients.
Certificate is the property of Assurance Quality Certification LLC and shall be returned immediately when demanded