

Certificate of Compliance CE

We hereby declare that medical products of class I according to the Medical Device Regulation -(Council Regulation 2017/745).

Certificate No.: CE-1431

Manufacturer

Name

Addres : A-6, Naraina Industrial Area, Phase-II, Delhi-110028, India

: CHHENNA CORPORATION

Product : Medical Recording Chart Paper, ECG Papers, TMT Papers, Laboratory Papers, EEG Papers, CTG Papers, ECG Jelly, Ultrasound Jelly, Sterile Jelly, Ultrasound Rolls, Disposable Electrodes, Medical Electrodes & Accessories, KY Jelly, Hand Sanitizer, Alcohol Sanitizer Wipes

The manufacturer's technical documentation as required for Medical Council according to the Medical Device Regulation -(Council Regulation 2017/745) has been reviewed and found to comply with the requirements for Class I Medical Devices Directive. Any significant changes in the design or construction of the product, not agreed upon by us, this declaration will lose its validity.

This certificate is issued under the following conditions:

- 1. It applies only to the quality system maintained in the manufacture of above referenced models and it does not substitute the design or type-examination procedures, if requested.
- The certificate remains valid until the manufacturing conditions or the quality systems are changed.
- 3. The certificate validity is conditioned by positive results or surveillance audits.

The CE mark as shown above can be used, under the responsibility of the manufacturer, after completion of an EC Declaration of conformity and compliance with all relevant EC Directives. The statement is based on a single evaluation of one sample of above mentioned product. It does not imply an assessment of the whole production.

Validity of this certificate can be verified at www.ukcertifications.org.uk/verify	
Date of Certification	17 th May 2023
1 st Surveillance Audit Due	16 th May 2024
2 nd Surveillance Audit Due	16 th May 2025
Certificate Expiry (subject to the company maintaining its	16 th May 2026
system to the required standard)	

Authorised Signatory



This certificate is the property of UK Certification & Inspection Limited and shall be returned immediately on request. 71-75 Shelton Street, Covent Garden, London, WC2H 9JQ, United Kingdom Website:- www.ukcertifications.org.uk, email:- info@ukcertifications.org.uk Company No. 11847851



Certificate of Registration

CHHENNA CORPORATION

A-6, NARAINA INDUSTRIAL AREA, PHASE-II, NARAINA, NEW DELHI-110028, INDIA

has been assessed and Certified by Otabu Global Services Pvt. Ltd. as meeting the requirements of:

ISO 13485:2016

Quality Management System for Medical Devices

For the following scope of activities:

MANUFACTURERS OF MEDICAL RECORDING CHART PAPER, ECG PAPERS, TMT PAPERS, LABORATORY PAPERS, THERMAL PAPERS, EEG PAPERS, CTG PAPERS, ECG JELLY, ULTRASOUND JELLY, STERILE JELLY, ULTRASOUND ROLLS, DISPOSABLE, ELECTRODES, MEDICAL ELECTRODES & ACCESSORIES

Issue No: 01 Date of Certification: 02 December 2022 1st Surveillance Due: 01 December 2023 Revision No(): NA 2nd Surveillance Due: 01 December 2024 Certificate Expiry: 01 December 2025 (subject to the company maintaining its system to the required standard)

Certificate Number: 1202QMMD457722 To Verify this Certificate please visit at www.otabuglobal.com







Managing Director

Otabu Global Services Private Limited

Validity of this certificate is subject to annual surveillance audits done successfully This Certificate Of Registration Remains The Property of Otabu Global Serivose Private Limited and Shall be Returned Immediately Upon Request Flat No. 954, Blk-d, Pkt 3, Bindapur, Dwarka, West Delhi, Delhi - 110059, India Email:- otabuglobal@gmail.com Website:-info@otabuglobal.com



Certificate of Registration

CHHENNA CORPORATION

A-6, NARAINA INDUSTRIAL AREA, PHASE-II, NARAINA, NEW DELHI-110028, INDIA

has been assessed and Certified by Otabu Certification Pvt. Ltd. as meeting the requirements of:

ISO 9001:2015

Quality Management System

For the following scope of activities:

MANUFACTURERS OF MEDICAL RECORDING CHART PAPER, ECG PAPERS, TMT PAPERS, LABORATORY PAPERS, THERMAL PAPERS, EEG PAPERS, CTG PAPERS, ECG JELLY, ULTRASOUND JELLY, STERILE JELLY, ULTRASOUND ROLLS, DISPOSABLE, ELECTRODES, MEDICAL ELECTRODES & ACCESSORIES

Issue No: 01 Date of Certification: 02 December 2022 1st Surveillance Due: 01 December 2023 Revision No(): NA 2nd Surveillance Due: 01 December 2024 Certificate Expiry: 01 December 2025 (subject to the company maintaining its system to the required standard)

Certificate Number: 1202Q169322 Validity of this certificate can be verified at www.otabucert.com







Dr. Anita Gupta (Managing Director)

*Validity of the certificate is subject to successful completion of surveillance audit on or before due date (in case surveillance audit is not allowed to be conducted, this certificate shall be suspended/withdrawal). *This Certificate of Registration remains the Property of Otabu Certification Pvt. Ltd. and shall be returned immediately upon request.

Otabu Certification Pvt. Ltd., RZ-9 (Ground Floor), Prem Nagar, Uttam Nagar, New Delhi-110059 (India) Email:- info@otabucert.com website:-www.otabucert.com