

# 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 : CHHENNA CORPORATION

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

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.
2. 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](http://www.ukcertifications.org.uk/verify)

Date of Certification 17<sup>th</sup> May 2023

1<sup>st</sup> Surveillance Audit Due 16<sup>th</sup> May 2024

2<sup>nd</sup> Surveillance Audit Due 16<sup>th</sup> May 2025

Certificate Expiry (subject to the company maintaining its system to the required standard) 16<sup>th</sup> May 2026

*Daniel..*

Authorised Signatory





# *Certificate of Registration*

This is to certify that

## **CHHENNA CORPORATION**

**A6, NARAINA INDUSTRIAL AREA, PHASE - II, NEW DELHI- 110028, INDIA**

has been independently assessed by QRO  
and is compliant with the requirement 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/ STRESS TEST PAPERS, LABORATORY PAPERS, THERMAL PAPERS, EEG PAPERS, CTG PAPERS, ECG GELS, ULTRASOUND GELS, STERILE GELS, ULTRASOUND ROLLS, DISPOSABLE ECG ELECTRODES, LIMB ELECTRODES, ACCESSORIES AND PFT MOUTHPIECES, EEG PASTE.**

Date of Certification: 3rd May 2025

1<sup>st</sup> Surveillance Audit Due: 2nd May 2026

2<sup>nd</sup> Surveillance Audit Due: 2nd May 2027

Certificate Expiry: 2nd May 2028

**Certificate Number: 305025050332MD**



Head of Certification

Validity of this certificate is subject to annual surveillance audits to be done successfully on or before 365 days from date of the audit.  
(In case surveillance audit is not allowed to be conducted; this certificate shall be suspended / withdrawn).

**The Validity of this certificate can be verified at [www.qrocert.org](http://www.qrocert.org)**

This certificate of registration remains the property of QRO Certification LLP, and shall be returned immediately upon request.

**India Office : QRO Certification LLP**

142, IInd Floor, Avtar Enclave, Near Paschim Vihar West Metro Station, Delhi-110063, (INDIA)

Website : [www.qrocert.org](http://www.qrocert.org), E-mail : [info@qrocert.org](mailto:info@qrocert.org)



# 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  
1<sup>st</sup> Surveillance Due: 01 December 2023

Revision No( ) : NA  
2<sup>nd</sup> 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](http://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](mailto:info@otabucert.com) website:-[www.otabucert.com](http://www.otabucert.com)