



Certificate of Compliance

CE

We hereby declare that the technical file of product class 1 complied with the requirement of the Medical Council Directives 93/42/EEC of June 1993

Certificate No.: 7466

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**

The Certification body has performed an audit of the above product quality system covering the design, manufacture and final inspection of the certified product. The quality system has been assessed, approved and is subject to continuous surveillance according to the Medical Council Directive 93/42/EEC of June 1993

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.
4. After fulfilling the relevant EU legislation of Class 1 in medical directive, the manufacturer shall affix to each device, of the referenced models.
5. 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 products. It does not imply an assessment of the whole production.

Validity of this certificate can be verified at www.ukcert.co.uk

Date of Registration	09 March 2019
1 st Surveillance Due	08 March 2020
2 nd Surveillance Due	08 March 2021
Recertification due (subject to the company maintaining its system to the required standard)	08 March 2022



Authorised Signatory

UK Cert Limited (UK)

5 Jupiter House, Calleva Park, Aldermaston, Reading Berkshire RG7 8NN, UK
Website:- www.ukcert.co.uk, Email:- info@ukcert.co.uk

This certificate is the property of UK Cert Limited (UK) and shall be returned immediately on request.
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/cancelled).



Certificate of Registration

CHHENNA CORPORATION

A-6, Naraina Industrial Area, Phase-II, 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: 19 November 2019

1st Surveillance Due: 18 November 2020

Revision No() : NA

2nd Surveillance Due: 18 November 2021

Certificate Expiry: 18 November 2022

(subject to the company maintaining its system to the required standard)

Certificate Number: 1119Q74119

Validity of this certificate can be verified at www.otabucert.com



Managing Director

Validity of this Certificate is successful Annual Surveillance audits to be done. 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



Certificate of Registration

This is to certify that the

CHHENNA CORPORATION

at

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

has been independently assessed and is
compliance with 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

Certificate Number: 8200

Date of Registration	: 19 November 2019
1 st Surveillance Due	: 18 November 2020
2 nd Surveillance Due	: 18 November 2021
Certificate Expiry (subject to the company maintaining its system to the required standard)	: 18 November 2022

Validity of this certificate can be verified at www.ukcert.co.uk



Murray James
Authorised Signatory

UK Cert Limited (UK)

5 Jupiter House, Calleva Park, Aldermaston, Reading Berkshire RG7 8NN, UK
Website:- www.ukcert.co.uk, Email:- info@ukcert.co.uk

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