

Certificate of Conformity

CE

Confirms that the products of class I according to the Medical Council Directive 93/42/EEC.

Certificate No.: CE-2074

Manufacturer

Name : Recorders & Medicare Systems (P) Ltd.

**Address : Regd. Office:- Plot No. 11, Information Technology Park,
HSI IDC, Sector-22, Panchkula-134114, Haryana, India
Works I: - Plot No. 9, Industrial Area, Phase I,
Panchkula-134113, Haryana, India**

Products : As Per Appendix-I & II

Complies with the requirements applicable to it

The manufacturer's technical documentation as required for class I, II & IVD device has been reviewed and found to comply with the requirements 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.
4. After fulfilling the relevant EU legislation, 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 product. It does not imply an assessment of the whole production

Validity of this certificate can be verified at www.ukcertifications.org.uk/verify

ate of initial registration

19th January 2022

Date of this certificate

19th January 2022

Certificate expiry

18th January 2023

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

18th January 2025

Daniel..

Authorised Signatory



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Appendix-I

Appendix to Certificate no.:- CE-2074
Applicant: Recorders & Medicare Systems (P) Ltd.
Address : Regd. Office:- Plot No. 11, Information
Technology Park, HSIIDC, Sector-22,
Panchkula-134114, Haryana, India
Works I: - Plot No. 9, Industrial Area, Phase I,
Panchkula-134113, Haryana, India



This certificate referred to above covers the following products like:

- **Product Group : POLYGRAPH**
Models :- RMS Polyrite D, RMS Polyrite AD, RMS Polyrite 2, 4, 8,16 Ch (Analog), RMS Polygraph A, RMS Polygraph 3A, RMS Physiograph D, RMS Physiograph AD, RMS Physiograph A, RMS Physiograph 3A,
- **Product Group : ELECTROENCEPHALOGRAPH (EEG)**
Models :- RMS Super Spec EEG 32, RMS Brain View Plus EEG 24, RMS Maximus 32, RMS Maximus 24, RMS SS Traveller 32, RMS BVP Traveller 24, RMS BVEC 24, RMS Ambulatory EEG, Maximus AEEG, RMS EEG 16CH (Analog)
- **Product Group : ELECTROCARDIOGRAPH (ECG)**
Models :- RMS Vesta 101, RMS Vesta 301i, RMS Vesta 302i, RMS Vesta 304i, RMS Vesta 121i, RMS Vesta 12C, RMS Vesta 12EC, RMS Ulterious 501
- **Product Group : DEFIBRILLATOR**
Models:- RMS Soter 101, RMS Soter 201, RMS Soter 301,
- **Product Group : AUDIOMETER**
Models :- RMS Hermes, RMS Hermes D, RMS Hermes E, RMS Tympanica, RMS Emissia
- **Product Group : STRESS TEST SYSTEM (TMT)**
Models :- RMS Vega 201, RMS Vega 202, RMS Vega 204, RMS Vega 301
- **Product Group : VITAL SIGNS PATIENT MONITOR**
Models :- RMS Phoebus P511, RMS Phoebus P512, RMS Phoebus P513, RMS Phoebus P515, RMS Phoebus P516, RMS Phoebus P517, RMS Phoebus P529, RMS Phoebus P123, RMS Phoebus P211, RMS Phoebus P121, RMS Phoebus P122, RMS Phoebus P311, RMS Ambulatory BP
- **Product Group : ELECTROMYOGRAPH (EMG/NCS/EP)**
Models :- RMS Aleron 201, RMS Aleron 401, RMS Salus 2C, RMS Salus 4C, RMS Salus 8C
- **Product Group : PULMONOLOGY**
Models :- RMS Helios 401, RMS Helios 701, RMS Helios 702
- **Product Group : HOLTER ECG**
Models :- RMS Cordis 3, RMS Cordis 12. RMS Holter-I, RMS ECG Holter-II



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Certificate of Conformity

Appendix-II

Appendix to Certificate no:- CE-2074

Applicant :

Recorders & Medicare Systems (P) Ltd.

Address :

Regd. Office:- Plot No. 11, Information
Technology Park, HSIIDC, Sector-22,
Panchkula-134114, Haryana, India
Works I: - Plot No. 9, Industrial Area, Phase I,
Panchkula-134113, Haryana, India



This certificate referred to above covers the following products like:

- **Product Group : POLYSOMNOGRAPH (PSG)**
Models :- RMS Quest 32, RMS Quest 24, RMS Quest 201, RMS Quest 101, RMS Asta 102, RMS Asta 202
- **Product Group : BRAIN EVOKED RESPONSE AUDIOMETER (BERA)**
Models :- RMS Medulla 201, RMS Medulla 202, RMS Medulla AD
- **Product Group : ELECTROCONVULSION THERAPY (ECT)**
Models :- RMS Ecton, RMS PC Ecton
- **Product Group : PSYCHIATRY**
Models :- RMS Quadramind (Multi Behaviour Therapy - MBT)
- **Product Group : BIO FEEDBACK SYSTEM**
Models :- RMS Relax 701, RMS Relax-I, RMS Relax-II
- **Product Group : X-RAY MACHINE**
Models :- RMS MDX-60, RMS MDX-100, RMS MDX-100DX, RMS MDX-100R, RMS MDX-100DX-FS, RMS MDX-100-FS, RMS MDX-300, RMS MDX-500, RMS HFX 3.5 E, RMS HFX 3.5 P
- **Product Group : C-ARM**
Models :- RMS Corus 6, RMS Corus 9, RMS Corus 9R, RMS Corus 9 PRO, RMS Corus 9 PRO+, RMS Corus 9 HD, Corus 9 HD 1K
- **Product Group : ELECTRONYSTAGMOGRAPH (ENG)**
Models :- RMS Gladius 201, RMS Gladius 401
- **Product Group : TRANSCRANIAL DOPPLER (TCD)**
Models :- RMS Spectra 102
- **Product Group : CLINICAL DIAGNOSTICS**
Models :- RMS Analytica, RMS Analytica 703, RMS Analytica 705, RMS Analytica 705i, RMS Urine Analyzer, RMS Orina EC, RMS Orina mini, RMS Orina prime, RMS Electrolyte Analyzer, RMS Hesita, RMS Hesita 360, RMS Proteios 30, RMS Fully Automated Hematology Analyzer, RMS Automated HbA1C Analyzer, Hemoglobin Meter,
- **Product Group : DIABETIC PRODUCTS**
Models :- RMS PeriScope, RMS D-RAP (Diabetes Risk Profiler), RMS CANWin, RMS PeriWin, RMS ThesioWin, RMS VarioWin

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