

Zenith Quality Assessors Pvt. Ltd. Certificate

Certificate No. CE/91/R/1357

Issued in cognisance with the requirements of the applicable directive MDD 93/42/EEC as amended, We certify that the technical file of the product/s

Medical Devices

(Refer Annexure-A for the list of medical devices covered under this certificate)

Manufactured by

RAJAS ENTERPRISES (INDIA)

at

**Nanhera Chowk, Nanhera, Post Office Kuldeep Nagar,
Ambala Cantt. 133004, Haryana, India**

Documented in line with the requirements of Annexure VII of Directive 93/42/EEC .

As per the declaration of the Manufacturer, the product falls in Class I device as per Annexure IX of MDD and does not fall in Point No. 5 of Annexure VII of MDD 93/42/EEC.

ZQAPL has performed the review of the technical file covering the requirements of the certified products as per Article 11.5

The detailed description of the review is presented in the final report 1357/01 which is enclosed with this certificate.

The manufacturer must inform ZQAPL of any plan for substantial changes to the technical documentation related to the product in order to examine whether this Certificate remains valid. Annual periodical audits will be held to verify the validity of this Certificate.

Initial Certification : 27th August, 2008
Valid until : 26th August, 2013



Management Representative
Zenith Quality Assessors Pvt. Ltd.

Further clarification regarding the scope of this certificate and the applicability of requirements may be obtained by consulting the organization. Lack of fulfillment of conditions as set out in the Certification Agreement may render this certificate invalid

Any significant changes in the design or process used to manufacture the products, or revisions to the standards referred above may require special audit by ZQAPL. The product liability rests with the manufacturer or his representative in accordance with standards. Above CE diagram is schematic and is used for reference only.

Zenith Quality Assessors Pvt. Ltd. Annexure - A

List of medical devices covered under this certificate

Certificate No. CE/91/R/1357

O.T.E. EQUIPMENTS

- Surgical operating tables (twin concealed cylinder)
- Surgical operating tables (chair position)
- Surgical operating tables (flex and reflex position)
- Surgical operating tables (trendlenburg/rev. trendlenburg position)
- Surgical operating tables (lateral position)
- Operation and Examination table (HI-LO)
- Obstetric labour table (Telescopic Type)
- Operating lights-Ceiling suspension shadow less operation light (twin model)
- Operating lights-Ceiling suspension shadow less operation light(20" dia. Single dome twin model)
- Operating light- Ceiling suspension shadow less operation light(22" dia dome with 4 reflectors)
- Ceiling suspension shadow less operation light (20" dia single dome)
- Ceiling suspension shadow less operation light (28" dia dome with 7 reflectors)
- Shadow less mobile operation lights (22" dia dome with 4 reflectors)
- Shadow less mobile operation lights (20" dia single dome)
- Shadow less mobile operation lights (14" dia single dome)
- Dressing drums & tray
- Syringe needle destroyer

HOSPITAL FURNITURE

- Hospital fowler bed (Deluxe)
- Hospital fowler bed (general)
- Attendant bed
- Hospital semi fowler bed (Deluxe)
- Hospital semi fowler bed (General)
- Hospital fowler bed (General)
- Instrument Trolley (With bowl and tray)
- Dressing trolley (with S.S. bowl and bucket)
- Crash cart
- Moy's trolley
- Bed side locker Deluxe
- Tri pot stick
- Instrument trolley (with bowl and tray)
- Dressing trolley (with S.S. bowl and bucket)
- Operation and examination table with hi and low system
- Obstetric labour table (Telescopic type)
- Emergency & recovery Trolley
- Examination couch

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DENTAL EQUIPMENTS

- Chair side unit
- Mini Dental Unit
- Physiological Dental Chair
- Electrically operated Chair
- Phantograph Dental Chair
- Dental Compressor
- Pneumatic Surgical Tool
- Dental chair
- Doctor Pneumatic stool
- Air rotor control
- Dental operating light
- Ceramic Spitton
- Air rotor Control box

LABORATORY EQUIPMENTS

a) **MICROSCOPES**

- Phoenix Student Field Microscope
- Student Microscope (Single Nose)
- Student Microscope (Single Nose) (Rajslab-03)
- Advance Student Microscope Erma Pattern (Condenser type)
- Student Microscope (Olympus Type)
- Junior Medical Microscope Erma Pattern (Moveable Condenser)
- Deluxe Advanced Student Microscope (Heavy Type)
- Laboratory and pathological Microscope
- Binocular research Microscope
- Projection Microscope (Rajslab-11)
- Projection Microscope (Rajslab-12)
- Projection Microscope with Halogen Bulb
- Dissecting Microscopes (Rajslab-14)
- Dissecting Microscopes (Rajslab-14)
- Film Strip and Slide Projector
- Metallurgical Microscopes
- Monocular Metallurgical Microscopes
- Binocular Metallurgical Microscopes
- Stereoscopic Metallurgical microscopes Research Microscope
- Zoom Stereoscopic Binocular Microscope
- Zoom Stereoscopic Trinocular Microscope
- Zoom Operating Microscopes
- Microscope with Computer System

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PLASTIC WARE

- 9001 Plastic Cylinders Graduated
- 9002 Plastic Cylinder
- 9003 bottles high density Polyethylene
- 9004 bottles high density
- 9005 plastic Y Shape Connector
- 9006 Plastic Connectors
- 9007 Beakers
- 9008 Plastic Wash Bottles
- 9009 Funnel
- 3-tiler Test Tube Stand
- Centrifugal Tube (Conical Bottom)
- Dropping Bottle
- Laboratory Tray
- Funnel Holder
- Plastic burette

GLASSWARES

- Funnel
- Sintered Glassware
- Stopcock
- Volumetric Glassware
- Low Actinic Amber Colour glassware
- Condensers
- Interchangeable Laboratory Glassware

LAB. EQUIPMENTS

- RE1001-Hot Air Oven
- RE 1002- Incubator
- RE 1003-B.O.D. Incubator
- RE 1004- Vertical Autoclave
- RE 1005-Water Bath
- RE 1006- Serological Water
- RE 1007-horizontal Laminar Air Flow
- RE 1008-Water bath rectangular (Single Wall)
- RE 1009-high Precision Water bath
- RE 10010-Tissue Floating Water Bath
- RE 10011-Water Bath Incubator Shaker
- RE 10012-Muffle furnace
- RE 10014-Ageing Oven Kag
- RE 10015-Humidity Chamber
- RE 10016-rotor Shaker (Fix Speed)
- RE 10017-Flash Point Apparatus
- RE 10018-Horizontal Laminar Flow Cabinet

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LAB. EQUIPMENTS

- Melting point apparatus
- Magnetic Stirrer
- Pippet Washer (Automatic) Syphon System
- Vacuum Pump Single Stage
- Shaking Machine (Rotary Shaker)
- Hot Plate (Round)
- Water Still (Stainless Steel Automatic)
- Centrifuge (Round)
- Heating Mental
- Soxhlet Extraction apparatus
- Lab Stirrer
- Adjustable Volume Micropipette- With Tip ejector and click stop
- Multi Channel Micropipette
- Water Distillation Apparatus

MEDICAL EDUCATION APPARATUS

PROJECTORS

- Projectors RE Model - A
- Projectors RE Model - B
- Epidiascope
- Slides (Rajasme -03,04,05,06,07)

MODELS

- Human Lungs
- RJ 8008 Human Kidney
- RJ 8008 Human Eye
- Animal Cell
- Flower Model
- Human Ear
- Model Denition
- Model Torso
- Skeleton
- Teeth & jaw

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REHABILITATION

- Invalid Wheel Chair Folding "Peadiatric"
- Invalid Wheel Chair Folding & Fixed Deluxe
- Invalid Wheel Chair Folding
- Invalid Wheel Chair Folding Deluxe (Full Chrome)
- Invalid Wheel Chair Folding Deluxe
- Invalid Wheel Chair Folding Commode
- Invalid Wheel Chair Non-Folding Special
- Invalid Wheel Chair Non-Folding Special (Iron Seat)
- Invalid Wheel Chair Non- Folding With Commode
- Fixed Wheel Chair Folding With Commode
- Wheel Chair Fixed Commode (Iron Seat)
- Folding Commode Deluxe full Powder Coating
- Back Rest
- Aluminium Crutches (pair) 25 mm (round)
- Elbow Stick
- Efoldng Walker Full Powder Coating (Adjusting)
- Walking stick powder stick C.R.C. (PIPS)
- Tri Pot Stick
- Heavy Duty Motorized Jogger (Rajasrg-19)
- Heavy Duty Motorized Jogger (Rajasrg-20)
- Foldable Jogger (Rajasrg-21)
- Foldable Jogger (Rajasrg-22)
- Foldable Jogger with Steel Rollers (Rajasrg-23)
- Foldable Jogger with Steel Rollers (Rajasrg-23)
- Multi Purpose Exerciser (6 in 1)
- Roller Skate Shoes
- Exercise ball
- Disposable Ice Packs
- Baby Nipple Thermometer
- Physio Ball
- Elbow Exerciser
- Wrist Roll Exerciser
- Knee Exerciser
- Wrist Circumductor
- Walking Sticks
- Grip Exerciser
- Rowing Machine
- Multi Exerciser Whole Body
- Super Nation Pronation
- Walking Sticks
- Dumble
- Weight Cuff Set
- Gonio Meter
- Multi Exerciser
- Walker
- Pado Cycle
- Wall Bar
- Rowing Machine

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REHABILITATION

- Parallel bar
- Ramp and stair Exerciser
- Ped Board
- Hand Exerciser
- Shoulder /Finger Exerciser
- Parallel bar
- Finger exerciser
- Walker
- Paschurul Mirror
- Multi hand Exerciser
- Parallel Bar
- Stair Exerciser
- Walker Two Wheeled (Chiled)
- Rollator Infant's

E.N.T. EQUIPMENTS

- Operating Microscope
- Swing and Rotation
- Motorized line Focusing
- Manual Line Focusing
- Counter balanced arm for easy variable angle viewing
- Fiber Optic Head Light
- Micro Motor For E.N.T.
- Halogen Exam light
- Head Light With Loupe
- Light Source
- Trocar For laparoscope
- Fibre Optic cable
- Halogen Head Light
- Halogen Operation Light
- Fiber Optic operating Light
- Shucman-pro
- Operating laryngoscope
- Fiber Optic Bronchoscope ad Eosophagoscope
- Fiber Optic Nasal Speculum
- Auditory Trainers

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EYE EQUIPMENTS

- Fiber Optic Cable
- Fiber Optic Head Light
- Fiber Optic Operating Light
- Halogen Operation Light
- Halogen Head Light
- Trial Lens Set
- Streak retinoscope
- Lensometer
- Light Source
- Binocular Loupe
- Halogen Exam. Light
- Head Light With Loupe
- Tonometer
- Binocular Indirect Ophthalmoscope
- Slit Lamp Microscope
- Keratometer
- Operating Microscope
- Ophthalmic Refraction Unit

SURGICAL EQUIPMENTS

a) Scissors

- Mayo
- Joseph
- Strully
- Braun Stadler Metzenbaum
- Beebee
- Heyman
- Joseph
- Dissecting
- Sim's
- Spencer
- U.S.A. patt

Haemostatic forceps

- Hartman
- Kelly
- Crile
- Collin (SI-032)
- Halsted Mosquito
- Collin (SI-301)
- Kocher (Ochsner)
- Lane

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Dressing and Tissue Forceps

- Standard
- Tissue
- Adson
- Russian
- Mcindoe
- Feilchenfeld
- Potts-Smith
- Thumb

Needle holders

- Castroviejo
- Crile-wood
- Si-049 size 21cm R
- Si-049 size 21 cm L
- Mathieu
- Mayo-Hegar
- Olsen-Hegar
- Reverdin
- Wangensteen

Retractors

- Roux (SI-100)
- Collin (SI-113)
- Deaver (SI-102)
- Deaver (SI-103)
- Farabeuf (SI-101)
- Janesn (SI-112)
- Kelly (SI-110)
- Kocher (SI-105)
- Langenback (SI-106)
- Mcdonald (SI-115)
- Richardson (SI-107)
- US army (SI-099)
- Hook (SI-104)
- Doyen (SI-109)
- Martin (Si-073)
- Weitlaner (SI-111)
- Balfour (SI-114)

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Hollowware

- SI-122
- (SI-125) Dressing Drum 25 X 20 cm
- (Si-124) Dressing Drum 24 X 24 cm
- SI-127 Kidney tray With cover
- SI-116
- SI-117
- SI-118
- SI-119
- SI-120
- SI-123
- SI-121
- (SI-126) Instruments Tray

Fisherman's Tools

- SI-130
- SI-131
- SI-132
- SI-133
- SI-134
- SI-135
- SI-136
- SI-137
- SI-138
- SI-139
- SI-140
- SI-141
- SI-142
- SI-143
- SI-144
- SI-145
- SI-146
- SI-147
- SI-148
- SI-149
- SI-150
- SI-151
- SI-152
- SI-153
- SI-128

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Jewelers tools

- SI-154
- SI-155
- SI-156
- SI-157
- SI-158
- SI-159
- SI-160
- SI-161
- SI-163
- SI-164
- SI-165
- SI-166
- SI-167

Pliers and scissors

- SI-168
- SI-169
- SI-170
- SI-171
- SI-172
- SI-173
- SI-174
- SI-175
- SI-176
- SI-177
- SI-178
- SI-179
- SI-180
- SI-181