CERTIFICATE

Certificate of Registration

This is to certify that The Quality Management System of Medical Devices

COMPETENT MEDICAL SYSTEM INDIA PVT LTD

177/SA/P30, Chandan Road, Indira Nagar, Lucknow-226016, Uttar Pradesh, India

has been assessed and found to be in compliance with the requirements of the standard

ISO 13485:2016

for the following scope :

Manufacturing of Modular Operation Theaters, Light Integrated Ceiling, Mounted Laminar Air Flow, Surgeon Control Panel, X-ray View Panel, Pressure Relief Dampers, Hatch Boxes, Storage Units, Writing Board, Single Arm Pendent, Double Arm Pendent, Bed Head Panels, Scrub Sink, Clean Room General Light, Medical Gas Pipe Line System

CERTIFICATE NO. : 25ZCZO0204M

ISSUED DATE : 06/02/2025
EXPIRY DATE : 05/02/2028

1ST SURVEILLANCE : 06/02/2026
2ND SURVEILLANCE : 05/02/2027

UKAC
UK ACKREDITERING CERTIFICATION LIMITED

Authorised Signatory

INTERNATIONAL QUALITY CERTIFICATION SERVICES UK LTD
272, Bath Street, Glasgow, G2 4JR, U.K.

This Certificate is intellectual Property of IQCS and can be maintained through surveillance and renewal audits.
Certificate should be returned to IQCS in case of non compliance of certification procedure.
Authenticity of this certificate can be verified at www.ukacert.co.uk / www.iqcscert.co.uk
The Registration is not a Product Quality Certificate.

CE CERTIFICATION

Certificate of Compliance

This is to Certify that the following designated products :

Modular Operation Theaters, Light Integrated Ceiling, Mounted Laminar Air Flow, Surgeon Control Panel, X-ray View Panel, Pressure Relief Dampers, Hatch Boxes, Storage Units, Writing Board, Single Arm Pendent, Double Arm Pendent, Bed Head Panels, Scrub Sink, Clean Room General Light, Medical Gas Pipe Line System

This certificate is issued under the following conditions:

1. **It applies only to the above referenced set of products mentioned above. The manufacturer is obligated to assure that all products of the respective model confirm to the type assessed by this certificate**
2. **The Certificate validity is conditioned by the positive result of the survellance audits.**
3. **The Certificate remains valid until the manufacturing conditions, the quality systems or relevant legislation are changed but until the 05/02/2028**
4. **After Fulfilling the EU legislation requirments, the manufacturer shall affix to each product of the above referenced models, CE Marking according to the following example**

Manufactured By

COMPETENT MEDICAL SYSTEM INDIA PVT LTD

177/SA/P30, Chandan Road, Indira Nagar, Lucknow-226016, Uttar Pradesh, India

Conforms with the Applicable requirements of Medical Device Directive MDD (93/42/EEC)

CERTIFICATE NO. : 25ZCZO0205C

ISSUED DATE : 06/02/2025
EXPIRY DATE : 05/02/2028

1ST SURVEILLANCE : 05/02/2026
2ND SURVEILLANCE : 05/02/2027

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CE CERTIFICATION

Certificate of Compliance

Manufactured By :

COMPETENT MEDICAL SYSTEM INDIA PVT LTD

Product Details

Operation Theater Department
(For New & Refurbishment of Old Installation)
Modular & Pre Fabricated Operation Theaters
Light Integrated Ceiling Mounted Planar Systems
Surgeon Control Panels
X-Ray View Panels
ICUS
Medical Gas Pipeline System
Bed Head Panels
Operating Magnetic Boards
Pressure Relief Dampers
Multi Movement Pendant Systems
Nurse Call System
Automatic Surgical Scrub Stations
Cleanroom General Lights
Sealed Swing Doors
Hermetically Sealed Sliding Doors
Hatch Boxes
Storage Units
Antistatic Conductive Floor Tiles Etc

Annexure-I Certificate No:-25ZCZO0205C

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CE CERTIFICATION

Certificate of Compliance

Manufactured By :

COMPETENT MEDICAL SYSTEM INDIA PVT LTD

Product Details

Medical Gases Pipeline System:

Medical Gas Pipeline Equipment

Multi-Movement Pendant Systems

Suction & Oxygen Therapy Products

Bed Head Trunking System

Medical Gas Outlets

Zonal Valve Box

Isolation Valve

Medical Alarm System

Manifold System

Emergency Manifold System

Bed Head Panel

Fully/Semi-Automatic Control Panel

Manual Control Panel

Other Hospital Peripherals :

Central Nurse Call System

Operating Tables, Hospitals beds, ICU Beds, Furniture, Trolleys

Operating & Examination Lights

Annexure-II Certificate No:-25ZCZO0205C

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CE CERTIFICATION

Certificate of Compliance

Manufactured By :

COMPETENT MEDICAL SYSTEM INDIA PVT LTD

Product Details

Services :

Design of System to International Standards
Supply and Installation of Equipment
Commissioning of Systems
Project Management
Refurnishing of Existing Facilities
Full Turnkey Project Solutions
Service Support and Maintenance

Specialized :

Cubical Partition Track System with Curtains
OT Light & OT Table, Scrub Sinks,
Ambulance Various Types of Flooring, Patient Monitor, Medical Equipment

Annexure-III Certificate No:-25ZCZO0205C

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