

CERTIFICATE



No. 240716.USQD12

Certificate's
Holder:

Unik Surgical Pvt. Ltd
2c/159, GD Mishra Path, New Patliputra Colony, Patna – 800013,
Bihar, India

Certification
ECM Mark



Product:

Electric bed, Trolley, Examination Couch, OT Table,
OT Light & General Hospital products

Model(s):

(see the following annex)

Verification to:

Standard:
EN 60601-2-52, IEC 60601-1, IEC 60601-1:2022,
IEC 60601-2-41, IEC 60601-2-46, IEC 60601-1-11:2015,
IEC 60601-1-2:2014

related to CE Directive(s):
R 2017/745 Annex I (Medical Devices Regulation)

Remark:

The manufacturer has voluntarily decided to submit its documents concerning the above-mentioned product for verification. Ente Certificazione Macchine confirms that the documentation made available and immediately returned to it, as containing sensitive data, meets the essential requirements of the above-mentioned directive/standard. The verification activity carried out exclusively concerned the technical documentation and no verification was carried out on the product. This document cannot replace the EC Declaration of Conformity. This document was issued in accordance with regulation RGVOL01 published on the website of www.entecerma.it and concerning voluntary certifications with a non-notified procedure.

Issuance date: 16 July 2024

Expiry date: 15 July 2029

For online check:



Approver
Ente Certificazione Macchine
Legal Representative
Luca Bedonni



Annex I



No. 240716.USQD12

Model(s):

Hospital Bed	ICU BED Motorized/Mechanical (ABS panel & ABS Railings)-USM-001, ICU BED Mechanical (ABS Panel)- USM002, ICU BED Mechanical (S.S. Bows)-USM-003, Recovery Bed Mechanical Fixed Height (ABS Panels)- USM-004, Hospital Fowler Bed (ABS Panels)- USM-005, Hospital Fowler Bed (SS Bows - Deluxe)- USM-006, Hospital Semi Fowler Bed (ABS Panels)- USM-007, Hospital Semi Fowler Bed Deluxe (SS Panels)-USM-008, Hospital Semi Fowler Bed (General) -USM-009, Hospital Bed Plain (General)-USM-010, PEDIATRIC BED- USM-011, Attendant BED- USM-012, Attendant BED General- USM-013, I.V. ROD FOR HOSPITAL BED- USM-015, Bed side Locker (Deluxe)- USM-025, Bed side Locker With Drawer & Railling-USM-026, Bed side Locker (std.)- USM-027
Table	Examination cum Gynae Table- USM-019, Gynae Examination Table (Plain)-USM-020, Examination Table (Plain)-USM-021, Examination Table with 2 Section-USM-022, OVER BED TABLE (Adjustable)- USM-030, OVER BED TABLE (Manually Adjustable)-USM-031, OVER BED TABLE-USM-032, Obstetric Labour Table Telescopic (Fixed Height)-USM-083, Obstetric Labour Table Telescopic (Adjustable Height)-USM-084, Obstetric Labour Table (Mechanically)-USM-085, Operation & Examination Table (Hi-Low) (72" X 20" X 32")-USM-087, Operation & Examination Table (72" X 20" X 32" Fixed Height)-USM-088, Universal Hydraulic Operating Table-USM-089, Universal Remote Control Operating Table-USM-090, Electric Surgical C- arm Operating Table -USM-091, C- arm Compatible Hydraulic Operating Table-USM-092, Table for doctor-USM-294, Table for nurses- USM-295, O.T. TABLE Minor- USM-318, O.T. TABLE Major - USM-319, Laboratory Table- USM-328, Wash Basin Stand (Single/Double) - USM-045, Patient's Revolving Stool (SS Top)- USM-048, Patient's Revolving Stool (Cushioned Top) - USM-049, Patient's/Visitor Stool -USM-050, Lab Technician Stool - USM-051
Trolley	ECG/UTILITY TROLLEY (Two Shelves)- USM-028, Medicine Trolley With 4 Drawer- USM-029, Monitor Trolley- USM-035, Mayo's Trolley for O.T.- USM-037, Instrument Mayo's Trolley Over The O.T Table (Mechanically)- USM-038, Instrument Mayo's Trolley Over The O.T Table (Manual)- USM-039, Instrument Trolley (Two Shelves)- USM-040, Dressing Trolley- USM-041, Solid Linen Trolley With Plastic Bucket - USM-046, Solid Linen Trolley With Canvas Bag - USM-047, Trolley For Oxygen Cylinder- USM-052, Emergency & Recovery Trolley (Hydraulic)- USM-076, Patient Trolley (Hi-Low) Mechanical- USM-077, Stretcher on Trolley With Matress - USM-078, Stretcher on Trolley - USM-080, Anaesthesia Trolley- USM-161, Medicine Trolley- USM-272, Surgical trolley- USM-275, Equipment trolley- USM-276, patient trolley - USM-277, Crash Cart In Powder Coated Frame- USM-033, Crash Cart In S.S. Frame- USM-034, Saline Stands- USM-036, Kick Bowl/bucket- USM-044, Wash Basin Stand (Single/Double)- USM-045, Baby Cradle - USM-053, Foot step single Powder Coated - USM-054, Foot step Double- USM-055, Bed Side Screen (4 Pannels) - USM-056
Examination Couch	Donor couch- USM-305, Exercise Bed/Couch- USM-165, Electric Blood Donor Couch- USM-075, Examination Couch with Gyane Cut- USM-023, Examination Couch- USM-024
OT Light	Ceiling Twin Cool Light CT - 20 (DX)- USM-105, Ceiling Cool Light C - 20 (DX)-vUSM-106, Ceiling (7-Ref.) Cool Light C-7 (DX/Reg.)- USM-107, Ceiling (4-Ref.) Cool Light C-4 (DX/Reg.)- USM-108, Mobile Light M - 14 (Reg.)- USM-109, Ceiling Cool Light (C - 19 Reg.)- USM-110, Ceiling Twin Cool Light CT- 4 + 4 (DX/Reg.)-USM-111, OT Light (LED) - 4 + 4 (Adjustable Colour Temperature)- USM-112, OT Light (LED) - 4 + 4 (Adjustable Colour Temperature)- USM-113, OT Light (LED) - 4 (Adjustable Colour Temperature)- USM-114, OT Light (LED) - 3M (Adjustable Colour Temperature)- USM-115, OT Light (LED) - 4M (Adjustable Colour Temperature)- USM-116, LED spot lights- USM-159, Examination Light- USM-191, LED light cure unit- USM-208, LED O.T. Light. (Double Dome)- USM-330
Chair	Invalid Wheel Chair Folding- USM-057, Folding Wheel Chair Chrome Plated- USM-058, Folding Commode Adjustable Height- USM-059

General Products	<p>Folding Commode Adjustable Height- USM-059, Inviold Walker- USM-060, Adjustable Walker (With Wheel Height Adjustable)- USM-061, Adjustable Walker (Without Wheel Height Adjustable)- USM-062, Folding Stretcher (Canvas) - USM-081, Folding Stretcher 2 Fold -USM-082, Obstetric Delivery Bed in 2 Parts (2 Section Top)- USM-086, Foot Suction. USM-121, Seamless Dressing Drums (S.S.) (all sizes)- USM-122, Instrument Sterilizer Electric (S.S.) - USM-123, Basin (S.S.)- USM-124, Kidney Tray (S.S)- USM-125, Sputum Mug (s.s.)- USM-126, Enema Can (s.s.) -USM-127, Lotion Bowl (s.s.) -USM-128, Cidex Tray - USM-129, Instrument Tray (s.s.) - USM-130, Catheter Tray (s.s.) Sizes : 16" x 4". -USM-131, Bed Pan (s.s.) Male/Female with Cover- USM-132, Urinal Pot (s.s.) Male/Female -USM-133, Formalin Chamber (with two trays)- USM-134, Formalin Chamber (with three trays)- USM-135, Instrument Cabinet- USM-136, Ward Lockers - USM-137, Ward Cabinet -USM-138, Waiting Area Chair-USM-140, Incubator. – USM-145, Steel Almirah- USM-320, Pediatric ICU Bed- USM-180, Resuscitation Bed- USM-181, Ophthalmic OT Table- USM-182, LDR/Delivery Bed- USM-183, Examination table with in-built IV Stand.-USM-189, Wheel Chair. (fixed)- USM-315, Phototherapy.- USM-142, Chair for doctor- USM-292, Chair for nurses-USM-293, surgical instruments and sets for each surgery/procedure for general OT.-USM-217, surgical instruments and sets for each surgery/procedure for Ortho OT.-USM-218, surgical instruments and sets for each surgery/procedure for Obstetrics and Gynaecology OT.-USM-219, Radiant Warmer. – USM-141, Tracheostomy set.-USM-220, Normal Delivery Kit.-USM-221, Episiotomy Kit.-USM-222, P.M. equipment .-USM-223, BP Handle.-USM-224, Artery forceps - straight.-USM-225, Artery forceps - Curved.-USM-226, Mosquito Forceps-Straight.-USM-227, Mosquito Forceps-Curved.-USM-228, Plain Dissecting forceps.-USM-229, Tooth dissecting forceps.-USM-230, right angle detector.-USM-231, right angle detector.-USM-232, Needle Holder-Large. -USM-233, Needle Holder-small.-USM-234, dissecting scissor 8".-USM-235, Allis tissue forceps.-USM-236, mayo's scissors.-USM-237, dissecting scissors 8" curved.-USM-238, stitch cutting scissors.-USM-239, guage cutting/bandage cutting scissors 12"-USM-240, sponge holding forceps-straight.-USM-241, sponge holding forceps-curved.-USM-242, kocher's artery forceps-curved.-USM-243, cat's paw retractor.-USM-244, ear speculum.-USM-245, nasal speculum-adult.-USM-246, nasal speculum-child.-USM-247, female metallic catheter.-USM-248, tongue depressor.-USM-249, Vaginal Speculum-large.-USM-250, vaginal speculum-small.-USM-251, vaginal speculum-cusco.-USM-252, removal of stitches tray.-USM-253, tuning fork (156 hz)-USM-254, tuning fork (512 hz)-USM-255, Percussion hammer.-USM-256, wooden tongue depressor.-USM-257, foot stool.-USM-258, gynaecological examination tray.-USM-259, spatula tray.-USM-260, Mouth Mirror.-USM-261, Punctum dilator.-USM-262, Nasal Speculum.-USM-263, laryngeal mirror.-USM-264, Water Bath. USM-146, Nasopharyngeal mirrors aural speculum siegles speculum.-USM-265, Magil's forceps.-USM-266, Reflex hammer- USM-267, Goinometer.-USM-268, jonson home probe.-USM-269, punch biopsy gun.-USM-270Table for nurses--USM-295, Chairs for patients/attendants-USM-296, cardiac table-USM-278, mortuary table.-USM-279, Bio Medical Waste Bins- USM-139, Shoulder Ladder- USM-149, Shoulder Wheel- USM-150, X-Ray View Box- USM-151, Weighing Scale. -USM-152, Stadiometer.-USM-153, ENT examination chair-USM-156, Trial lens set with trial frame Adult & Child-USM-157, Small Incision Cataract Surgery (SICS) Set-USM-158. Foetoscope-USM-160, Static Cycle- USM-162, Gripped Hand Exerciser -USM-163, Parallel Bar.-USM-164, Quadricep Chair.-USM-166, Walker and Tripods.-USM-167, Mirror with Stand.-USM-168, Hot Air Oven. – USM-144, Infantometer.-USM-196, Overhead Pulley.-USM-171, Wall ladder finger exerciser-USM-281, Finger exerciser web-USM-282, Shoulder Pulley-USM-283, Reciprocal walker-USM-284, Exercise coucduh-USM-285, Roof/well mounted single piece curtain to ensure privacy-USM-290, Colour coded bins-USM-291, Hub cutter/needle cutter-USM-307, Laminar air flow bench-USM-311, Jointed Dressing Drum. (all sizes)-USM-316, laryngoscope adult.-USM-206, laryngoscope paediatric.-USM-207, oxygen hood.-USM-214, pneumatic drill.-USM-215</p>
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