

Certificate of Compliance



Confirms that the products Medical Equipments, Products & Spares of class I according to the Medical Council Directive 93/42/EEC of June 1993

Certificate No.: CE-2213

Manufacturer

Name : **United Surgical Industries**

Address : **Head Office - 445 F.I.E. Patparganj Industrial Area,
Delhi-110092 , India
Factory Address Pioneer Complex, 12/77-80, Site-IV,
Sahibabad Industrial Area, Distt - Ghaziabad (U.P) – 201010**

Products Name & Models : **As per appendix of page 1 Of 3**

Applicable Standards : **IEC 60601-1, IEC 60601-2-46, IEC 60601-1-2, IEC
60601/2/41/IEC 60529/IEC 60601-1-38, IEC 60601-2-52,
EN ISO-14155-2:2003, ISO-13485:2012**

Complies with the requirements applicable to it

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 manufacturer's technical documentation, as required for **Class I** device, has been reviewed and found to comply with the requirements.

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. 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.co.uk/verify

Date of initial registration	01 st January 2016
Date of this certificate	14 th September 2018
Certificate expiry	31 st December 2019
Recertification due (subject to the company maintaining its system to the required standard)	31 st December 2019

Daniel..

Authorised Signatory



Certificate of Compliance

Appendix-1

Appendix to Certificate no.:- CE-2213

Manufacturer :

United Surgical Industries

Address:

Head Office - 445 F.I.E. Patparganj Industrial Area, Delhi-110092, India
Factory Address Pioneer Complex, 12/77-80, Site-IV, Sahibabad Industrial Area, Distt - Ghaziabad (U.P) - 201010



This certificate referred to above covers the following products like:

Product Name & Models:

• **Hospital Beds (Manual / Mechanically / Electric)**

USI-3003H, USI-3001H, USI-3001, USI-993H, USI-993, USI-997H, USI-997, USI-992H, USI-992, USI-990H, USI-990, USI-943H, USI-943, USI-963H, USI-963, USI-1001, USI-984HE, USI-984E, USI-984ER, USI-984H, USI-984, USI-908, USI-908H, USI-1053, USI-1002, USI-965E, USI-965H, USI-965, USI-1003, USI-1051, USI-1012, USI-1011, USI-1064, USI-1010

• **Associated Accessories of Hospital Bed**

Mattress USI-5001A /B/C/D, USI-5013, USI-5014, Balken Beem Frame USI-5005, Lifting Pole USI-5006, Bed Side Railing & USI-5020/5021/5022/818, IV Rod USI-5002, Mosquito Net Poles USI-5008

• **IV Stands USI-1039, USI-1037, A/B/C/D Bed Side Screens USI-1027 / 1028, Bed Side Lockers USI-1018/1019/949, 1017, Wash Basin Stands USI-1044/1046, Over Bed (Cardiac) Tables USI-1020/1021/1068/948, Patient Carrying Trolleys / Stretcher Trolleys USI-E3 / E4 / 1069, 1069A/1016 / 962 / 1008/985 / E8**

• **Patient Transfer System**

USI-991/ 909Folding Stretchers USI-1095A/1095/1096, Scoop Stretcher - 987A/987M, Spine Board - USI-988, Stair Chair - 910/911

• **Baby Cradle / Basinet & Wheel chairs**

USI-1038/958/1042, Wheel Chairs USI-910/809/901/907LABH/681/904B/ 691/609GC / 1040



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Appendix-2

Appendix to Certificate no.:- CE-2213

Manufacturer :

United Surgical Industries

Address:

**Head Office - 445 F.I.E. Patparganj Industrial Area, Delhi-110092 , India
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This certificate referred to above covers the following products like:

Product Name & Models:

- **Labour Tables / Delivery Beds**
USI-E7/ H7/1090/1091/1092/1093/1097
- **Examination Tables / Couches & Dialysis Beds**
USI-1065/1066/954/1094 / 1063 / 1062
- **Anaesthesia Trolleys - USI-938/941, Emergency Trolleys - USI-939/940, Medicine Trolleys - USI-1057**
- **Case History Trolleys USI-D3/D4, Trolley for Oxygen Cylinder USI-1047**
- **X-Ray View Boxes (Fluorescent Tube/CFL/LED) USI-971/972/973**
- **Instrument / Dressing / Mayo's / Utility / Laparoscopic/Monitor Trolleys**
USI-805/956/1022/1006/1025/976 /1014
- **Foot Steps USI-1029/1030, Soiled Linen Trolley with canvas bags/Buckets**
USI-1048/1067
- **Patients / Lab Technician /Surgeon / Attendant Stools**
USI-1031 /950/1036/1075/ 1055
- **Kick Bowl / Bucket USI-1032/1033, Crash Cart USI-1070, Scrub Station**
USI-970 / 969
- **Portable / Vertical / Horizontal Auto Claves and Sterilizers**
USI-1073/2551/2502/3010
- **Aerosol Disinfectant/ Fogger / Fumigator**
USI-2552/2553
- **Suctions Machines Electric / Manual USI-1071/1072/ Univac - II**
/983/812/9B
- **Dressing Drum USI-2501 / Kidney Tray USI-2505 / Basins USI-2508 / Instruments Tray USI-2505 / Sputum Mug USI-2510 / Bowl USI-2511 / Urine Pot USI -2507/ Bed Pan USI-2506 / Waste Receptacle USI-1074**

Daniel..

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Certificate of Compliance

Appendix-3

Appendix to Certificate no.:- CE-2213

Manufacturer :

United Surgical Industries

Address:

Head Office - 445 F.I.E. Patparganj Industrial
Area, Delhi-110092, India
Factory Address Pioneer Complex, 12/77-80,
Site-IV, Sahibabad Industrial Area, Distt -
Ghaziabad (U.P) - 201010



This certificate referred to above covers the following products like:

Product Name & Models:

- **Instrument Cabinet** USI-1045, **Needle and Syringe Destroyer** USI-806, **Bio Medical Waste, Bin** USI-807/808
- **OT Tables Manual / Hydraulic / Electric / Electro Hydraulic**
USI-2001/2003/2005/5010 / 5011 / 2008 / 6010/ 7011
Orthopedic attachment / Spin Attachment / Neuro Attachment
USI-2006 / USI-S / USI-N
- **OT Lights, and Examination Light Halogen /LED**
USI-LED B4/B3/M1/W1/M2/MB3/MB4/B3+B3/B4+B4/LED
36S/LED30S/LED20S/LED30D /LED 36D/LED20D/LED30+20/LED20M/LED
30 M /LED 19M / LED 15M / LED 48S / LED 48D



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