

Certificate of Compliance



We hereby declare that the technical file of product complied with the requirements Medical Devices 93/42/EEC as Amended 2007/47/EC.

Certificate No.: CE-3385

Manufacturer

Name : **Medi Waves Inc.**

Address : **Head Office: B-68, G. T. Karnal Road Industrial Area,
Delhi - 110 033, India
Factory: Plot No. 92, Sector 57, Phase IV, Kundli,
Sonapat - 131 028, Haryana, India**

Product : **Hospital Furniture, Hospital Bed Accessories, Ward Care Equipments,
Patient Transport System, Doctor's Room Equipments, Operation
Theatre Equipments, Infant Care Equipments, Rehabilitation &
Physiotherapy Equipments, Patient Monitoring Equipments & Other
Surgical Equipments
(more detail as per appendix page I to V)**

Applicable Standard: **IEC 60601-1, IEC 60601-2-46, IEC 60601-1-2, IEC 60601-2-41,
IEC 60529, EN ISO 14155-2:2003, ISO 13485:2003**

The quality system file has been assessed, approved and is subject to continuous surveillance according to the Council Directive on Medical Devices 93/42/EEC as Amended 2007/47/EC.

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.

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

Date of Certification	02 nd August 2022
1 st Surveillance Audit Due	01 st August 2023
2 nd Surveillance Audit Due	01 st August 2024
Certificate Expiry (subject to the company maintaining its system to the required standard)	01 st August 2025



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Certification & Inspection



Certificate of Compliance

Appendix-I

Appendix to Certificate no.:- CE-3385

Manufacturer :

Medi Waves Inc.

Address :

Head Office: B-68, G. T. Karnal Road Industrial Area,
Delhi - 110 033, India

Factory: Plot No. 92, Sector 57, Phase IV, Kundli,
Sonepat - 131 028, Haryana, India



This certificate referred to above covers the following products like:

Products & Models :-

Hospital Furniture	
Hospital Bed Plain (Bed Stead)	HFO01 MHB-12
Hospital Bed with Backrest.	HFO01A
Semi Fowler Bed (General, Deluxe & ABS Panel)	HF003, HF004 & HF004A MHB-09, MHB-10, MHB-11
Fowler Position Bed (General, Deluxe & ABS Panel)	HF005, HF006 & HF006A MHB-05, MHB-06, MHB-07, MHB-08
ICU Bed Mechanical & Electric	HF007 & HF008, EHB-01, EHB-02, EHB-03, EHB-04, MHB-01, MHB-02, MHB-03, MHB-04
Delivery Bed /Birthing Bed	HF062
Paediatric Bed, Plaster Table	HF002 & HF002A PHB-01, PHB-02
Foldable Bed	MHB-13
Attendant Bed	MHB-14
Electric Bath bed	EBB-01, EBB-02
Hospital Bed Accessories	
Mosquito Net Poles	-
Balka Frame	-
Bed Elevator	-
Collapsible Side Railing	HBA-03, HBA-04
Lifting Pole	HBA-01
Mattress	HBA-05, HBA-06, HBA-07
Pillow Burn Cage	-
IV Rod	HBA-02
Baby Crib Attachment	-
ABS Head & Foot Panel	HBA-08, HBA-09
Ward Care Equipments	
Bed Side Table, Bedside Locker (General & Deluxe)	HF033 & HF034 HWE-07, HWE-08, HWE-09
Bed Side Screen 3 Fold & 4 Fold	HF052 & HF052A HWE-10, HWE-11
Bed Side Stool	HF026 HWE-24
Over bed Table (Patient Food Trolley)	HF022 & HF035 HWE-12, HWE-13, HWE-14, HWE-15
Baby Crib & Baby Bassinet	HF036 & HF036A PHB-03, PHB-04
I V Stand or Saline Stand	HF047 HWE-22, HWE-23
Oxygen Cylinder Trolley	HF043, HWE-25
Waiting Area Chair	HWE-35, HWE-36
Patient Transport System	
Patient Transport Systems	HF009 PTT-01, PTT-02
Patient Stretcher Trolley (Fixed & Hi-Low)	HF 048 & HF050 PTT-06
Emergency & Recovery Trolley Foldable Stretcher	HF042, PTT-03, PTT-04, PTT-05, AST-01, AST- 02, AST-03, AST-04

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Appendix-II

Appendix to Certificate no.:- CE-3385

Manufacturer :

Medi Waves Inc.

Address :

Head Office: B-68, G. T. Karnal Road Industrial Area,
Delhi - 110 033, India
Factory: Plot No. 92, Sector 57, Phase IV, Kundli,
Sonepat - 131 028, Haryana, India



This certificate referred to above covers the following products like:

Products & Models :-

Doctor's Room Equipments	
Examination Table	HF010, EHC-03, EHC-05, EHC-06
Examination Couch (General & Deluxe)	HF011 & HF013, EHC-01, EHC-02, BHC-02
Examination Couch Three Sections	HF012
Examination Cum Gvnae Table	HF015
Gvnae Table or Gynecological Couch	HF016
Instrument Cabinet. Medicine Cabinet or Storage Cabinet	HF049, HWE-40, HWE-41
Crash Cart	HF051, HWE-37, HWE-38
Instrument Trolley	HF017, HWE-30, HWE-31, HWE-32
Instrument/Medicine Trolley	HF023, HWE-29
Mayo Trolley or Mayo Instrument Trolley	HF021, HWE-34
Dressing Trolley	HF020, HWE-28, HWE-33
Utility Trolley or Ward Trolley	HF024
Drug Trolley, Linen Trolley or Soiled Linen Trolley	HF019, HWE-19, HWE-20, HWE-21
Bowl Stand Single & Double	HF038, HF039 & HF040, HWE-16, HWE-17
Revolving Stool	HF028, HWE-05, HWE-06
Surgeon's Stool	HF031, HWE-03, HWE-04
Doctors Operating Stool	HF032
Foot Step Single Single & Double	HF044 & HF045, HWE-01, HWE-02
Kick Bucket. Swaddling Table	HF037, HWE-18
Blood Donor Chair. Waste Bin	HWE-39, HWE-26, HWE-27
X-Ray View Box	HF040
Wheel Chair	HWE-42, HWE-43
Operation Theatre Equipments	
Operation Theatre Table	HF060
Operation Theatre Table Hi - Low	HF063
Obstetric Cum Gynae Table. Delivery Bed or Obstetric Labor Table Fixed	HF014, GHC-01, GHC-02, GHC-03, GHC-04
Obstetric Labor Table Hi-low	HF014A, OHT-01, OHT-02, OHT-03, OHT-04
Hydraulic Operation Table	HF061, HST-01
Infant Care Equipments	
Open Care System	P-001
Radiant Warmer	P-001A
Phototherapy Unit (LED, CFL, UV)	P-003, P-003B & P-003C
Incubator	P-002A

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Appendix-III

Appendix to Certificate no.:- CE-3385

Manufacturer :

Medi Waves Inc.

Address :

Head Office: B-68, G. T. Karnal Road Industrial Area,
Delhi - 110 033, India
Factory: Plot No. 92, Sector 57, Phase IV, Kundli,
Sonepat - 131 028, Haryana, India



This certificate referred to above covers the following products like:

Products & Models :-

Infant Care Equipments	
Infant Resuscitation Unit / Suction Units (Electric & Manual)	P-023
Cardio Toco Granh	P-018
Foetal Donoler/Monitor. Apnea Monitor	P.005, P.006. P-007, P-008, A100H
Vacuum Extractor	P-024
Bilirubinometer	P-004 ,MBJ-20
Oxygen Hood	P-016A
Baby Bassinet	P-010
Digital Weighing Scales for Baby & Adult	P-014 ,P-015 & P-016
Baby Infantometer	P-017A & P-017B
Physiotherapy Equipments	
Short Wave Diathermy 250 & 500 Watts	PH001 & PH002
Traction Unit	PH008A
Muscle Stimulator	PH-004
Diagnostic/ Treatment Model, Interferential Therapy Unit PH005 (IFT)	PH005
Muscle Stimulator (Therapeutic)	PH006
Digital Ultrasonic. Tens 4 Channel	PH008
Continuous Passive Motion System (CPM)	PH009
Slimming Machine	PH010A
Hydro Collator Hot Pack	PH011
Wax Bath	PH012
Traction Table	PH013
Shoulder Wheel Wall Mounting & Axial Model	PH-014 & PH-016
Rowing Machine	PH-015
Cold Therapy	-
Contract Bath	-
Ankle Exerciser Grin Exerciser with Base	-
T.Pullev	-
Micro Wave Diathermy	-
Infra-Red Laser	-

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Appendix-IV

Appendix to Certificate no.:- CE-3385

Manufacturer :

Medi Waves Inc.

Address :

Head Office: B-68, G. T. Karnal Road Industrial Area,
Delhi - 110 033, India
Factory: Plot No. 92, Sector 57, Phase IV, Kundli,
Sonepat - 131 028, Haryana, India



This certificate referred to above covers the following products like:

Products & Models:-

Monitor Equipments	
Portable Health Checkup Station	SK-GS6
Pulse Oximeter	VS-2000
ECG Machine	ECG-301 , ECG-601 ,& ECG-1201
Infusion Pump	HK-100I
Vital Sign Monitor	VS-2000, PM-5000
Multi Parameter Patient Monitor	PM-5000, AQUA-15
Defibrillator	DM-7000 & AED-7000
Syringe Pump	HK-400
Anaesthesia Machine	S6100 , S6100A , S6200A
HFNC Machine	HFV-03
Oxygen Concentrator	MEDIAIR 5Ltrs & MEDIAIR 10Ltrs
C-Pap Machine	BCPAP-09
Bi-Pap Machine	CPAP-09 & BCPAP-09
Other Surgical Equipments	
O. T. Light & Examination Lights (Halogen/ LED)	-
Autoclave/ Sterilizers	-
Syringe Needle Destroyer	OT-006
Hub Cutter	OT-006A
Blood Bank Refrigerator	-
Digital & Analog Weighing Scales	-
Height Stand/ Stadiometer	-
X-Ray View Box	-
Non - Mercury Blood Pressure Apparatus	AXD-804 , CROWN

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