

Compliance Certificate

We certify that the technical documentation of the products, drawn by the applicant is in compliance with the specified Directive and Standards 93/42/EEC as Amended 2007/47/EC

HARDIK MEDITECH

Plot No. 92, HSIIDC, Sector-57, Phase-IV,
Kundli, Sonipat, Haryana (INDIA)

Has been assessed and conforms to:



Applicable to Products:

AS PER ANNEXURE 1st and 2nd

“Validity of This Certificate is Subject to Annual Surveillance Audits Done Successfully”

Certificate Number: HM2301032

Certificate Issue Date: 14/02/2023

1st Surveillance Due on: 01/02/2024

Certificate Expiry Date: 13/02/2026

2nd Surveillance Due on: 01/02/2025

The technical documentation shows that the product compliance with the essential safety requirements recognized as giving presumption of compliance with the essential requirements in the listed EU Directive. The technical documentation of the products relate only to the products listed in this certificate. Any Significant Modification will make this Certificate invalid. The product liability rests with the manufacturer of this representative in accordance with the Medical Device Directive 93/42/EEC



Certification Manager

Deutsche Accreditation Board

Otto-Hang-Ring 6, D-81739 Muenchen, Germany
E-mail: info@dabaccreditation.org, Website: www.dabaccreditation.org

The client is requested to check the above certificate details at board website www.dabaccreditation.org under the heading of registration details by entering their certificate number and inform us in case of any discrepancy at our above email id.

HARDIK MEDITECH

Certificate Number: HM2301032

PRODUCT(S) LIST

ANNEXURE 1ST

Weighing Scale (Digital & Mechanical), Infant Weighing Scale, Bathroom Scale, Hanging Scale, Platform Scale, Adult Scale, BMI Scale, Mother & Child Scale, Digital Personal Scale, Measuring Equipments, Height BIPAP Interface masks, Stand with and without Weight Scale Examination Light (Halogen & LED), Operation Light (Halogen & LED) Magnifying Lamp, X-Ray Film Viewer, Stethoscope Operation Theatre Table, Modular Operation Theatre Equipment, Hospital Furniture, Physiotherapy Equipments, Respiratory Equipments, Path Lab Equipments, Baby Care Equipments & Medical Equipments, Stop Watch, Thermometer, LED Torch, Stadiometer, Infantometer, HBNC Kit & Baby Kit, Pre School kit Dark Room and General Accessories for X Ray Machine, Surgical Operating Microscope, ENT Equipments, Oxygen Flow Meter, Two & Triple layer Surgical Mask, N-95 Mask, Surgical Instruments, Disposable Bed Sheet, Head light, Wooden Toys Disposable Gowns, Sterilized Surgical Gloves, Personal Protective Cover All & Non-Rebreather Mask, Empty Oxygen Cylinder, Non-Rebreather Mask Non-Invasive Ventilation Mask, Bipap/ CPAP Mask, Central Venous line Double Lumen, IBP circuit, Oxygen Mask (pediatric), HFNC Canulae (pediatric), HFNC Circuits, HME (Heat Moist Exchanger) Filter pediatric, HEPA filter, NIV Mask (pediatric), Ventilator tubing, Disposable pediatric, Naso-Gastric (NG) Tube, Suction Catheter, Paediatric ECG lead, Urinary catheter, Nasal prongs Neonatal, Intracath 26G/Venflans, Pediatric Microdrip Sets, Pediatric Oropharyngeal Airways, Double Lumen PICC Lines, Lederflex Long IV Canula, Endotracheal Tube, PMO Lines, 3 Way Canulas, Orogastric Tubes, Suction Catheters, Closed suction Catherers Neonatal, Vaccupack Suction Tube, Pediatric Spacers, IV Drip Sets with Drip Controllers, Tegaderm, Pediatric Urosac Bags, CPAP Dispoable Circuits for Paediatric, Ventilator circuits with Heating wire & Humidifiers, HME Viral Filters for expiratory Limb, Nebulizer & Vaccine Carrier-Sparx VC-200, Autoclave Machine, Boyles Apparatus, Otoscope, Laryngoscope, Audiometer, Autoclave HP Medicine Refrigerator, Slit lamp, Streak retinoscope, tonometer, Spot light, Pedestal light, Wood lamp, Lumbar Belts & Neck Belts/Cervical Collar Anklet (Tubular Support) Belts, Led Head Light & Elbow Support Belts Ophthalmoscope, Stethoscope, Nebulizers (Electric) & Infusion Pump

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ANNEXURE: 2nd

PRODUCT(S) LIST

- | | |
|----------------------------|--|
| 1. Microscope Slides | 25. Funnel |
| 2. Microscope Cover Glass | 26. ESR Pipette |
| 3. Cardboard Slides Mailer | 26. Vaccine Carrier- Sparx VC-200 |
| 4. Slides Box | 27. Needle Holder |
| 5. Test Tube | 28. Hemocytometer Set |
| 6. Glass Tube | 29. Swab Applicator |
| 7. Tube Stopper | 30. Beaker |
| 8. Test Tube Rack | 31. Flask |
| 9. Centrifuge Tube | 32. Cylinder |
| 10. Centrifuge Tube Rack | 33. Medicine Cup |
| 11. Sample Cup | 34. Microhaematocrit Tube |
| 12. Urine Test Tube | 35. Mortar With Pestle |
| 13. Cuvette | 36. Slides Staining Jar |
| 14. Petri Dish | 37. Wash Bottle |
| 15. Culture Plate | 38. Cell Culture Flask |
| 16. Filter Tip | 39. Pipette Filler |
| 17. Pipette Tip Box | 40. Westergren Glass Tube |
| 18. Embedding Cassette | 41. Serological Pipette |
| 19. Cryovial Tube | 42. Sharp Container |
| 20. Inoculating Loop | 43. ESR Fast Detector |
| 21. Pipette Tip | 44. Burette |
| 22. Pasteur Pipette | 45. Condenser |
| 23. Micropipettor | 46. Vacuum Blood Collection Tube |
| 24. Reagent Bottle | 47. Reagent Strips For Urinalysis |
| | 48. HCG |
| | 49. Micropipettes (SPARX SMP 100
SPARX SMP 200) |

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