

Priya Consultancy (I) Pvt. Ltd.



MEDICAL APPARATUS INDUSTRY

COMPANY SETUP

Register company: Pvt Ltd / LLP / Partnership / OPC

GST, PAN, TAN, IEC (for imports/exports)

Udyam / MSME registration

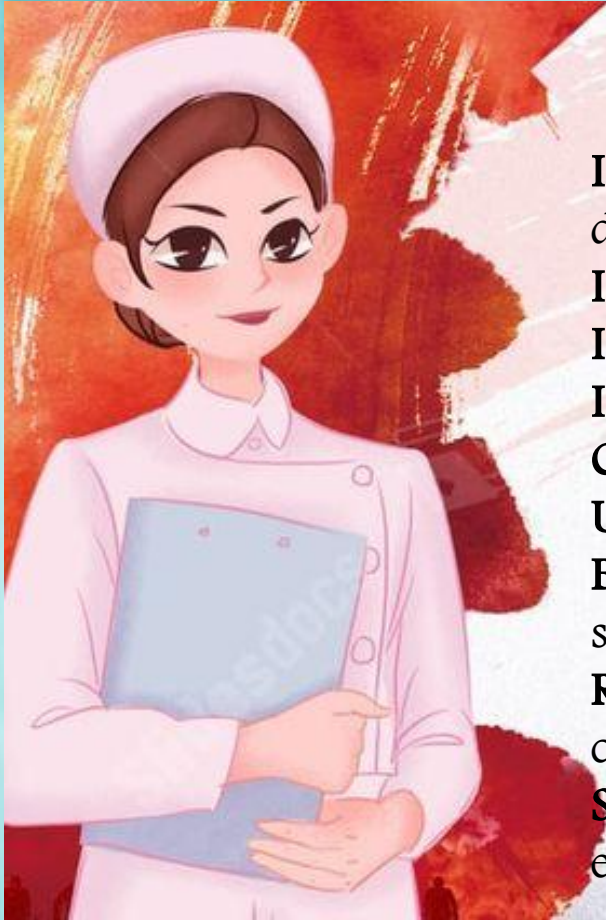
Bank current account

EPF & ESIC registration (for employees)

Group Insurance & General Insurance

LICENSES & APPROVALS

- **Industrial Land & Factory License** (Labour Dept.)
- **Pollution Control Board (CTE & CTO)** – if effluent or emissions
- **Fire NOC**
- **Medical Device Manufacturing Licence** – CDSCO (Central Drugs Standard Control Organisation, India) under **Medical Device Rules 2017**
- **ISO 13485 Compliance** (mandatory for most devices)
- **BIS / CE / US FDA approvals** – based on target markets
- **PESO Licence** – if flammable materials are used



CERTIFICATIONS

ISO 13485 – Quality management for medical devices

ISO 9001 – General quality system

ISO 14001 – Environment

ISO 45001 – Occupational Health & Safety

CE Marking – for export to Europe

US FDA 510(k) / PMA approval – for USA export

BIS (ISI Mark) – if notified under Indian standards

REACH / RoHS – if using electronic/chemical components

Social Compliances – SA8000, SEDEX, BSCI (for exports)

DIGITAL SYSTEMS

- **Website** – product catalog, compliance, certificates
- **ERP Software** – production, HR, inventory, sales (Zoho, SAP, Oracle, Tally ERP)
- **IPR Requirements:**
 - Trademark – brand & logo
 - Patent – unique medical apparatus innovation
 - Copyright – manuals, website, software
- **Barcode & QR Code** – GS1 India registration (for packaging, device tracking)





PLANT, MACHINERY & EQUIPMENT

- Clean Room Facility (ISO Class 7/8)
- Injection Moulding Machines (if plastic-based devices)
- Assembly lines & automation
- Sterilization Units – Ethylene oxide (EtO), Gamma radiation, Autoclaves
- Testing & Calibration Equipment
- Packaging Machinery – sterile blister packs, sealing machines
- Air Handling Units (HVAC for clean rooms)
- Safety & Firefighting systems



TESTING LABORATORY

- **Mechanical Testing Lab** – strength, durability
- **Electrical Safety Testing (IEC 60601)** – for electronic medical devices
- **Biocompatibility Testing** – cytotoxicity, irritation, sensitization
- **Microbiology Lab** – sterility, endotoxin testing
- **Calibration Lab** – equipment precision verification
- **Tie-up with NABL accredited labs** – for advanced testing



TRAININGS

- GMP & ISO 13485 awareness training
- Clean room practices & hygiene training
- Safety & emergency response training
- Medical device design & risk management training
- Firefighting & first-aid
- Social compliance awareness



CONSULTANTS REQUIRED

- **Project Consultant** – layout, clean room design, machinery selection
- **Regulatory Consultant** – CDSCO, US FDA, CE approvals
- **Environmental Consultant** – pollution, waste handling
- **ISO Consultant** – ISO 13485, 9001, 14001, 45001
- **PESO & Fire Safety Consultant**
- **HR & Social Compliance Consultant**
- **Website & ERP Consultant**
- **IPR Consultant** – patents, trademarks



THANK YOU PRIYA GROUP TEAM

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