



**JOHARI**<sup>®</sup>  
medtech

Electronic Medical Device  
Manufacturer

# 40+ Years of Medical Device Manufacturing Excellence

Johari Digital is one of the leading companies offering **Design, Engineering and Manufacturing Services for Medical Devices.**

Our State of the Art **Medical Device Manufacturing** facility in India is in compliance with MDSAP, ISO 13485:2016 and FDA GMP standards and processes and spans over 65,000 square feet.

**Design and Engineering** teams operating from :

- Technology Development Centre - **Europe**
- **DSIR Recognized R&D** and Product Engineering Centre, India
- Centre of Excellence, **IIT Jodhpur**

**Business Development** teams operating from :

- INDIA • USA

We are 100% Export Oriented Unit (EOU).





# Certifications and Robust Processes

Johari meets the ISO standards relevant to the product, as well as cGMP requirements



Medical Device Single Audit Program (MDSAP) is QMS audit that enables our company to meet the regulatory requirement for **Australia, Canada, Brazil Japan and USA.**



This certification confirms that we follow standard processes of **medical devices design and development, production, storage and distribution, installation and servicing**



FDA 510K clearances prove that our devices meet quality standards of FDA and are **safe to known risks and effective for the intended use.**



CE mark signifies that products sold in the EEA have been assessed to meet high safety, health, and environmental protection requirements.



**100,000**

Products Installed  
Worldwide

**500+**

Active Customers  
Worldwide

**145+**

Commercialized  
Products

## Our Services



# Full Turnkey Medical Device Manufacturing



State-of-the-art manufacturing setup located in India



Dedicated R&D center in Europe



Strategically positioned to serve business partners around the globe



Helping customers achieve highest levels of manufacturing efficiency



Optimizing cost and providing support for regulatory & quality certification enabling quick Go-To-Market



Delivering value throughout the product life cycle



Ever-growing network of experts, including intellectual property

## Key Service Offerings



### Design and Engineering

Design & Engineering solutions to accelerate the life cycle of medical device development and optimize manufacturing costs. Our designing, prototyping, and value engineering services ensure fast-paced Go-to-Market and compliance to ISO : 13485 guidelines.



### Contract Manufacturing

Contract Manufacturing solutions for global medical device manufacturing companies as well as innovative start-ups. Our facility is equipped with advanced capabilities to manufacture complex to high-volume products.



### Regulatory and Quality Assurance

Strategic guidance to clients at every stage of the product development process. Our regulatory experts have extensive experience in multiple regulatory jurisdictions, including MDSAP. We minimize the client's Time to Market with streamlined & well managed process for regulatory approvals

# Adding value across Product Lifecycle



## Value Engineering

We create products that offer enhanced functionality, flawless aesthetic appeal, and ease of use. Compliance with the highest standards of quality at minimal cost to deliver remarkable products is our core strength.



## Upgrade Existing Product

Our Research and Development team includes highly qualified professionals with expertise in leading-edge innovation and technology to modify/customize your existing products for better aesthetics and improved performance at an optimized cost of production



## New Product Introduction

NPI involves moving from prototypes to full scale production through multiple phases such as Engineering Verification, Design Verification and Product Validation. This includes checking the capabilities, machines and production line efficiency for a new product, critical analysis and mitigation of risks to ensure efficient mass production

# Manufacturing Capabilities





# In-house Capabilities

## Design and Development



### R&D - (Serbia, Europe)

- World class technology development center in Europe
- Ability to quickly turn concepts into detailed product design
- 3D printing and quick prototype
- Technology research & product concepts



### Industrial Design

- Brainstorming and creative sessions
- Ideas & conceptualizing
- CAD design and drafting
- Molds and tools design
- Exploring colors, materials & finishes



# 200+

Project Completed !



# 20+

Patented  
Enclosures  
Designs

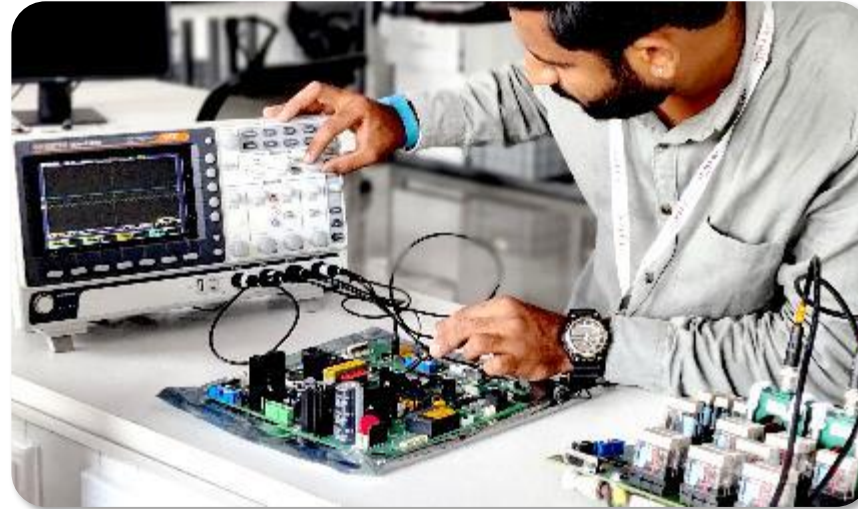
# In-house Capabilities

## Design and Development



### Electronics PCB and Software Design

- Ability to quickly turn concepts into detailed product design
- Printed Circuit Boards (PCB) layout and design
- Broad prototype preparation
- Embedded software and UI design



### Product Engineering (India)

- Mechanical part and tool development
- Enclosures and housing
- Cable and wire harness, clipping and stripping.
- EMI/RFI shielding



**100%**

Focus on  
Medical Device  
Design and  
Manufacturing



**35+**

Engineers in Design  
and Development

# In-house Capabilities

## Manufacturing



## PCB Manufacturing & Testing

- Capacity of 1000+ PCB production per day
- Class 100,000 clean room electronics manufacturing
- 01005 (0201) Components placing
- Mount Flip Chip, BGA, MELF, CSP
- RF Microelectronics, High Density Interconnects (HDI)
- PCB Size from Micro to 500mm x 450mm
- Flexible, Rigid, Backplanes and Multilayer PCBs
- Automated placement capacity, 32000 CPH



## 5 Parallel Product Assembly Lines

- Multiple assembly lines for simultaneous integration of simple to complex devices.
- Full assembly from PCBA to final integration
- Box Build: Injection molding, casting, sheet metal
- Mechanical parts manufacturing
- Electrical & mechanical assembly
- Packaging assembly & hardware installation



# In-house Capabilities

Pro Active Quality Control System, Error Tracing & Change Management



## Quality Assurance

- Quality Control (Raw Material, Final Product)
- Validation and verification
- Product functional & performance testing
- Labeling control & device history record
- CAPA management
- Regular supplier audits & gap analysis
- Process validation

## Change Management & Traceability

We Maintain **DMR** and **DHR** documents. We readily address and record changes required in the product at pre and post-market stages. Our documentation process, including ECR (Engineer Change Requirement document) and ECN (Engineer Change Note), is strictly maintained to track every big and small change at every step. The documentation process assures traceability over years





# In-house Capabilities

## Regulatory and Certification Services



### Go-To-Market Assistance

We offer strategic guidance to our clients at every stage of the product development process.

- Regulatory Support
- Respect for IP Protection
- Post Market Surveillance



### Certification Assistance

- 510K, PMA, CE, UL, FDA, UDI applications
- Medical device risk management certifications
- RoHS, IEC 60601 certification
- ISO 13485 implementation and certification
- Technical File/Dossier File/Medical Device File



**17+**

**US FDA 510K  
Certifications**



**145+**

**Commercial  
Products Launched**

# Supply Chain Management

Well Established Qualified Vendors

170

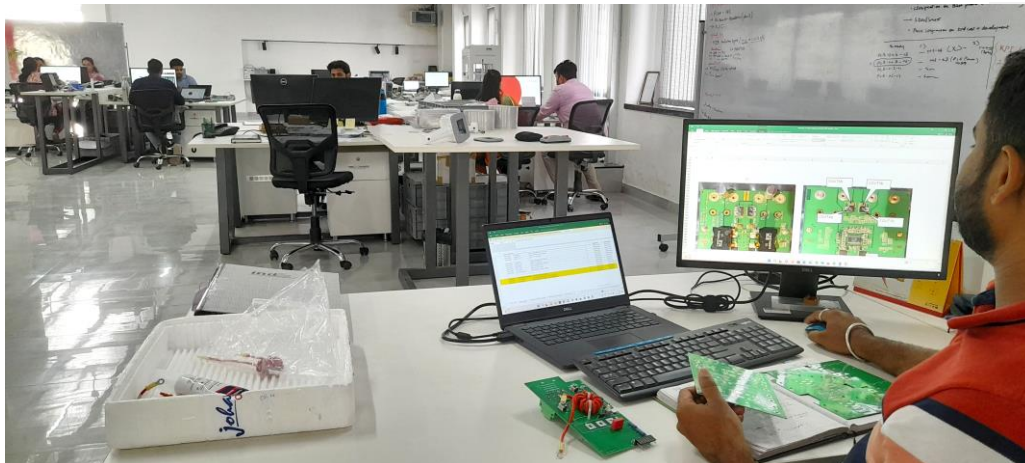
Frontline  
Vendors

400 +

Strong Bench of  
Registered Vendors

Well-defined Vendor Qualification  
Process and Supplier Rating

Capability to plan and execute multiple /alternate sourcing of raw materials



We have strong sourcing team managing multiple suppliers & vendors for :

- Molding and Casting
- Sheet Metal
- Multiple Job Works
- Electricals and PCB's
- Off the Shelf Supplies
- Consumable Supplies

## Proven Experience

500 + molded plastic parts for Hand Held, Wearable, Desktop, Floor Models medical devices.



Laser Printing  
Cutting

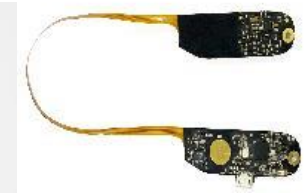


ABS Molded Complex Plastic  
Parts, Poly Carbonate Parts  
Table Top Medical Devices



Large Plastic and Sheet  
Metal Parts for Floor  
Models

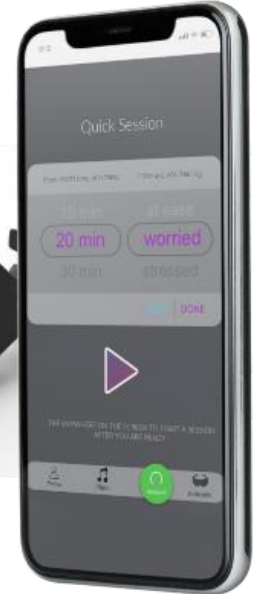
Smart wearable device with complex and micro electronics



01005 Components

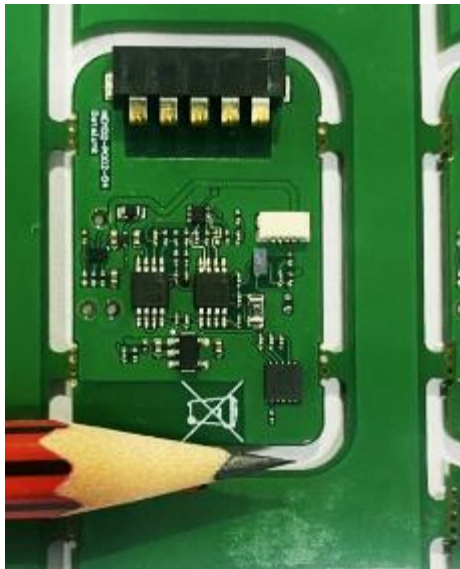


Bluetooth  
Connectivity



# Proven Experience

Microelectronic Components



Microelectronic PCB





# Technology Landscape



# Technology Offerings

With 100,000+ product installations worldwide, Our expertise in medical device manufacturing cuts across industries.



Life Science



Medical Diagnostic



Hospital Equipment



Home Healthcare



Physiotherapy



Medical Aesthetics



Wellness



Personal Care

# Our Technology Landscape | Product Folio



**HOMOGENIZATION**  
- Life Science



**COLORIMETRY**  
- Bio Science



**SPECTROPHOTOMETRY**  
- Life Science



**ELECTROCHEMISTRY**  
- Diagnostic



**MUSCLE STIMULATION**  
- Sport Medicine

## Our Technology Landscape | Product Folio



**MICRO-CURRENT**  
- Beauty & Skin Care



**COLORIMETRY**  
- Bio Science



**MICROWAVE STERILIZER**  
- Hospital Equipment



**ELECTROTHERAPY**  
- Physical Medicine &  
Rehabilitation



**CRANIAL ELECTRICAL  
STIMULATION**  
- Stress Relief



# IP Protection

Having a long history of handling our partner's IP we understand the value of sensitive data. Along those lines, we pro-actively establish, monitor, and enforce security protocols to protect client's data



Strong IT and  
Access Control



Strong Non-Disclosure  
Agreements



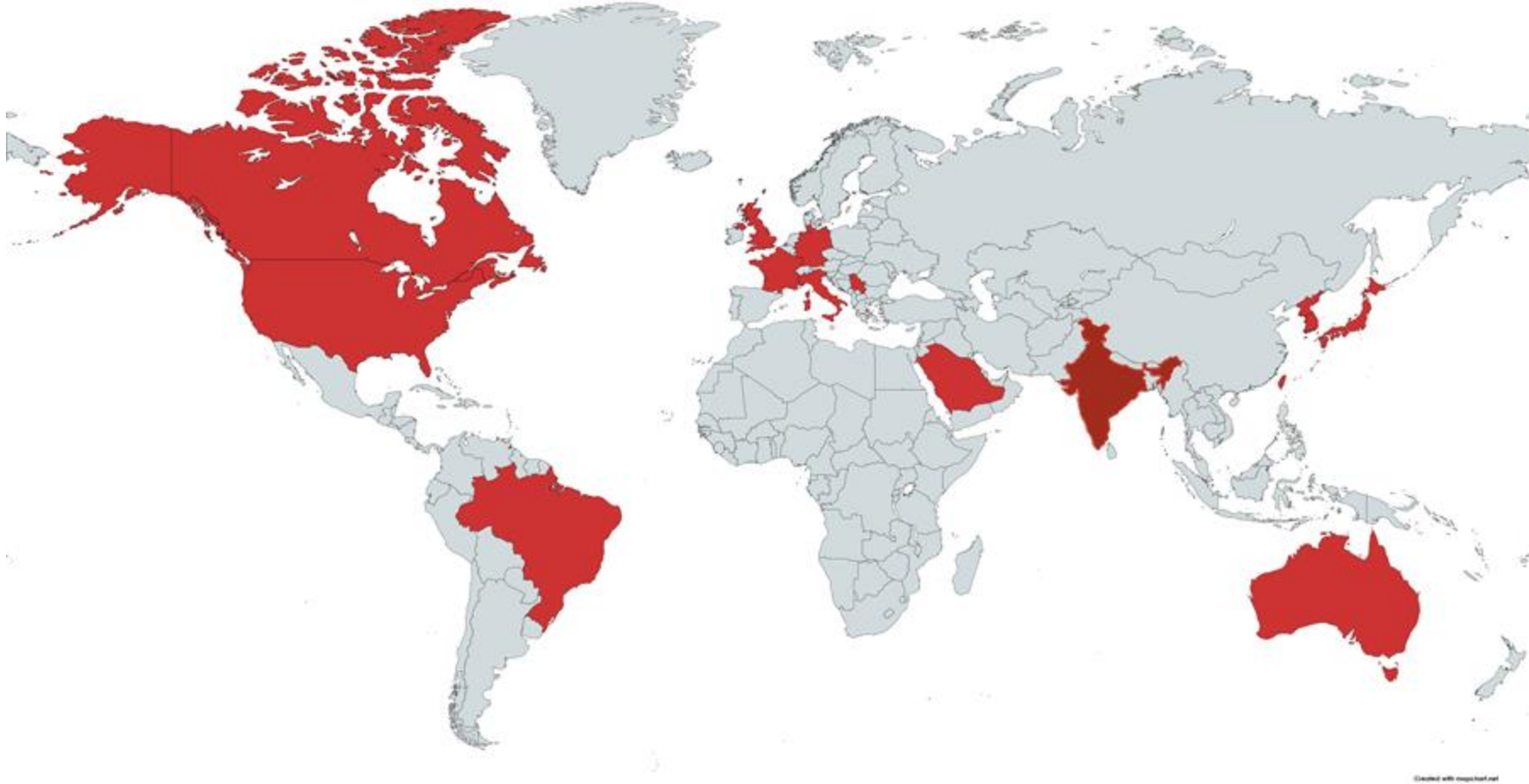
Enforced Data  
Security Policies



In-House IP Experts &  
Legal Consultants



# Global Presence



USA | Canada | Brazil | Australia | Japan | India | UK | France | Germany | Serbia | Italy | Korea | Thailand | Malaysia | Taiwan | Saudi



**Thank You**