



CONTACT



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<https://mithunkumarl.github.io/net-boot/>

SUMMARY

Resourceful R&D Design Engineer with over 3+ years of experience in medical device development and mechanical design. Currently contributing to AUSA Medical Devices Pvt. Ltd., where I assist in complaint investigations, implement corrective actions, and ensure compliance with ISO 13485 and ISO 14971 standards. Previously, at Mechtek strong foundation in risk management and change management processes.

EDUCATION

- B.E MECHANICAL ENGINEERING
- VVIT College, Bangalore.
- 2022 - 2025
- Board-VTU
- 8.2* CGPA

MITHUN KUMAR L R&D DESIGN ENGINEER



EXPERIENCE

ENGINEER DESIGN-R&D

AUSA MEDICAL DEVICES PVT. LTD.
BANGLORE.

April 2022 - Present

COMPANY PROFILE:

Manufacture of medical appliances and instruments and appliances for measuring Checking testing, and other purposes.

Major service providing are BSC BD INARI MEDICALS
BR SURGICALS ETC....

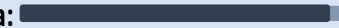
RESPONSIBILITY:

- **Assisted investigations into medical device complaints**, utilizing root cause analysis and 7 QC tools and implement corrective and preventive actions (CAPA).
- **Developed and maintained compliance documentation**, such as Standard Operating Procedures (SOPs) to support continuous compliance assurance and regulatory audits.
- Performing IQ/OQ/PQ, DOES, PCS Quality (Gauge R&R Capability Study (CP CPK), for metal & plastic components.
- Writing quality testing procedures and checking quality to ensure compliance, R&D review, Design control, Risk management (ISO 14971).
- **Collaborated cross-functionally** with R&D, regulatory, and quality teams to drive investigations, resolve product issues, and recommend corrective actions, including customer bulletins and field corrective actions.

- DIPLOMA (TOOL AND DIE MAKING AND ENGINEERING)
- College- GTTC Bangalore.
- 2015 - 2018
- Board-BTE
- 75%
- SSLC
- Cordial High School Bangalore.
- Year-2015
- Board-KSSEB
- 59.68%

LANGUAGES

English: 

Kannada: 

Hindi: 

Tamil: 

Telugu: 

SKILLS

- SolidWorks
- AutoCAD
- Microsoft tools
- Product design
- Cost estimation
- Project planning
- DFM, FMEA

Sound knowledge

Geometric dimensioning & tolerancing ISO 13485, ISO14971:2012, CAPA DFMEA, DFM, Gauge R&R, IQ/OQ/PQ Qualification.

- **Reviewed and updated risk management documentation**, including PFMEAs, DFMEAs, and risk management plans, to ensure alignment with ISO 14971 requirements, facilitating continuous improvement in product safety and performance.
- Contributed to change management activities using PDM, including Engineering Change Orders (ECOs) and Product Change Notifications (PCNs).

■ **DESIGN ENGINEER** MECHTEK-BANGLORE, India
07/2019-01/2022

COMPANY PROFILE:

Mechtek is an Engineering Solutions for Pharmaceutical Industries Around the World in Includes Blister Packing Machines and R&D Machines Also Forming Change Part.

RESPONSIBILITY:

- Development of CAD 3D models for product, fixture, mold & preparation of detailed manufacturing drawings.
- 2D design for CNC wire cut EDM machine, Bending drawing for sheet metal.
- Developing the Mold design with DFM
- Selected manufacturing methods, fabrication and product designs with care for internal cost controls and government standards.
- Modification of design as per customer demand Detailing for production drawing.
- Troubleshooting For Thermoforming Machine and Change Parts.
- Modification of design as per customer demand Detailing for production drawing.

ACHIEVEMENT

- Received STAR PERFORMER OF THE QUARTER YEAR-2023 For Taking the Sidekick Project to The Production Level.
- Got GOLD AWARD In Sandhar Group for QUALITY CIRCLE.
- Got BRONZE AWARD In Sandhar Group For KAIZEN.

Personal Details

Father's name: N LOKESH

Date of birth: 11/11/1998

Nationality: Indian

Gender: Male

Religious: NAIDU, EDEGA

Marital Status: Un-Married

- **TOOL AND DIE MAKER SANDHAR TECHNOLOGIES**
BANGLORE India 106/2018-06/2019

COMPANY PROFILE:

1Year implant Industrial Training in sandhar components unit-1 attibele Tool Maintains of Die Casting, Mould Tool & Press Tool.

RESPONSIBILITY:

- Assembly of All Type of Tools
- Blue Matching of Mould Tool and Die Casting Tool.
- Finding the mold defects and manufacturing problems solving by why-why analysis including corrective and preventative action plan.
- Polishing of Core and Cavity.
- Die and Punch Grinding in Press Tool.
- Studied blueprints, sketches and specifications to plan sequences of operations for fabricating tools, dies and assemblies.
- Developed specifications from general descriptions for specialty tools and drew or sketched design of product.
- Study of metals to be used based on hardness, heat tolerance and other properties.

MACHINING KNOWLEDGE:

- Milling machine
- Grinding machine
- Lathe machine
- Conventional / non-conventional machines
- Dro-machines



Declaration regarding:

I hereby certify that the information above is accurate to the best of my knowledge and belief.