

# MEDICAL CONTRACT MANUFACTURING

# Clean Room Injection Molding, Assembly & Injection Tool Shop



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**VEM GROUP** 







20+ Years of experience

Team of highly experienced Managers and Experts in the field

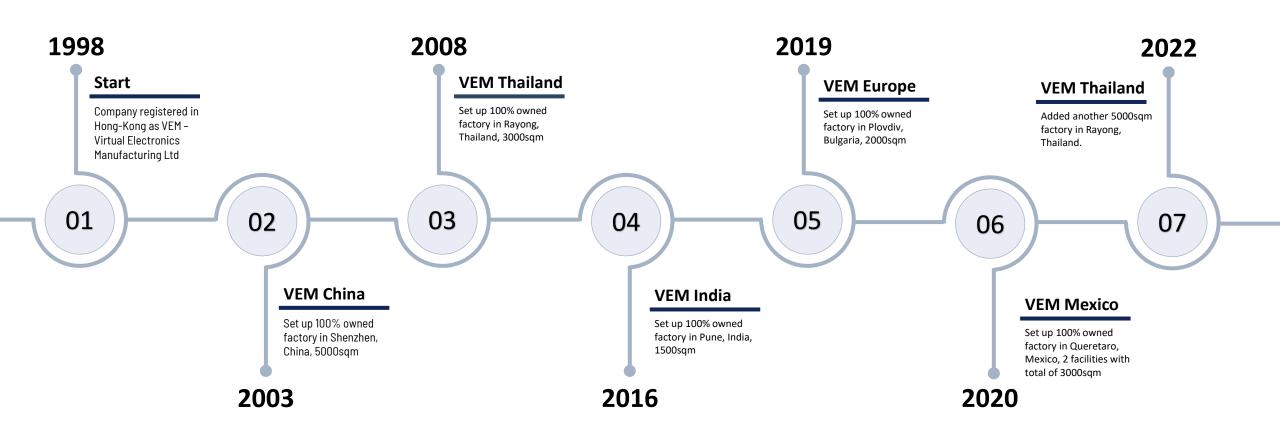
Manufactured over 8000 molds

High tech tool shops

Contract tool-shops for warranty and modifications



#### **HISTORY - VEM GROUP**



FACTORY



## **Environmental Sustainability**

- VEM Thailand factory 1 is fully equipped with Solar panels.
- VEM Thailand factory 2 is fully equipped with Solar panels.







## ISO 13485

#### Certificate of Registration

#### QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

bsi.

VEM (THAILAND) CO., LTD 427 Moo. 2 Mapyangporn, Pluakdaeng, Rayong 21140 Thailand

Holds Certificate Number:

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

The manufacture of plastic injection parts and assembly for medical ventilator system

MD 683191

For and on behalf of BSI: Gary E Slack, Seni

Original Registration Date: 2019-01-09 Latest Revision Date: 2021-12-15



|               | 20                         |
|---------------|----------------------------|
| nya           | Estade                     |
| 9             |                            |
| ior Vice Pres | ident - Medical Devices    |
|               | Effective Date: 2022-01-09 |
|               | Expiry Date: 2025-01-08    |
|               | Page: 1 of 1               |

...making excellence a habit."

## ISO 7 / Class 10,000



## ISO 8 / Class 100,000

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|-------------------------------------|--|--|--|
|                                     | TEST   | NEBB   |  |
| 9                                   | QV TEST CO., LTD   | Certification Number: CR3647   |  |
|                                     | CERTIFICATE  | OF COMPLIANCE  |  |
|                                     | VEM (Thailand) Co., Ltd.   |  |  |
| 9                                   | Cleanroom#2  |  |  |
|                                     |  |  |  |
| ğ                                   | ISO Class 8 Clea   | anroom, In Operation   |  |
| acceptanc<br>was perfo<br>standards | As per requirements of ISO 14644-1: 2015 (E), the designated area listed above has<br>acceptance criteria for Class 8 at $\geq 0.5 \ \mu m$ , $\geq 1.0 \ \mu m$ and $\geq 5.0 \ \mu m$ , under in operation condition<br>was performed and was obtained in accordance with the current edition of the NEBB p<br>standards for certified testing of cleanroom, and as outlined in the above standard and the r<br>attested to in the Report No: C220135. |  |  |
|                                     |  | Contraction of the second seco |  |
| ä                                   |  | Performance to   |  |
| Ğ                                   | Date of Certification:   | Mukdavan Prakobvaitayakit  |  |
| õ                                   | 28 August 2022   | NEBB Certified CPT Professional  |  |
| ğ                                   | QV TEST CO., LTD.<br>1804 SOI NAWABIN HI YAKA AWABANA HUNG KOM, ANGKOK, THAILAND 10230<br>Tel: +46 2 600 JSS2, +669 4485 5599  |  |  |
| C                                   |  |  |  |

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**ENGINEERING** 

- Help sourcing ROHS/ REACH/ USP class VI compliant materials
- Biocompatibility and Cytotoxicity testing certificate of raw materials is ensured wherever required
- FMEA and FDM to identify and eliminate potential problems in manufacturing
- Support 3D printed prototypes



PROTOTYPING

Validate the product and manufacturing capabilities Quick and efficient prototyping technologies:

- Soft steel prototype molds
- Aluminum prototype molds
- 3D printed prototypes (Steel and Plastic)



#### PROTOTYPING

# Printing plastic prototypes for validation & functional testing.

- PLA
- ABS
- PETG
- Nylon
- TPU and TPE



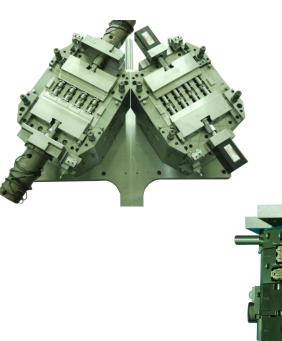


#### **MOLD MANUFACTURING CAPABILITIES**

## **Expertise in:**

## 2K Molds, Multi cavity molds, High precision molds









#### **MOLD MANUFACTURING CAPABILITIES**

## **Mold Maintenance:**

## Internal maintenance & modification capabilities







#### **MOLD MANUFACTURING CAPABILITIES**

# **3D Steel Printing**

- Mold steel inserts
- Optimized conformal cooling channels
- Significant reduction in production cycle time





#### **MOLD MANUFACTURING**

In house toolmaking facilities in China/India/Bulgaria

China: https://youtu.be/57rX3deD1AQ India: https://youtu.be/cHnLGGuvFIs Bulgaria: https://youtu.be/4EqW5crDHQ8



#### **INJECTION MOLDING**

- 30+ Injection molding machines
- Machine range 5 TON to 850 TON
- Fully equipped with desiccant dryers, HR controllers, MTC, Bimetallic barrel





**ISO 7 CLEANROOM** 

### Clean Room ISO 7 / Class 10,000 (Video tour: https://youtu.be/-jyKbd6Vmsg)









**ISO 7 CLEANROOM** 

#### High Level of Production Automation on our product lines.







**ISO 8 CLEANROOM** 

## Clean Room ISO 8 / Class 100,000 Molding (Video tour: https://youtu.be/-jyKbd6Vmsg)







**CLEANROOM** 

## Assembly Example Ventilator Connector



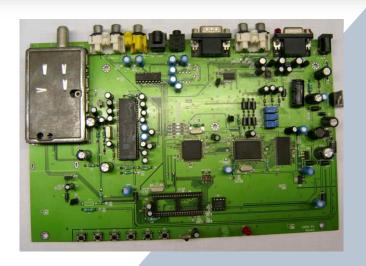
Injection Molding Over Molding Assembly Testing Final Packaging

#### **PCBA SERVICES**



## We provide PCBA related services:

- PCBA production
- Box built products, manual assembly
- ICT/FCT testing and IC programming
- Tester building and maintenance









IQ / OQ / PQ

Process qualification as per medical standards

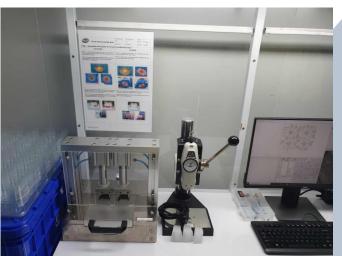
- Installation Qualification
- Operation Qualification using DOE
- Performance Qualification



**PROCESS CONTROL** 

Fully equipped measurement laboratory SPC online wherever needed Inspections 24 hours











## We ship all over the world INCOE Terms as required by customers







**CUSTOMER** 







Point-of-care PCR Home Device





**REFERENCE PARTS** 

Consumable Parts for Auto-Ventilator

