



Product Engineering

- Mechanical design in 3D modelling with CAD software
- Tolerance and mold flow analysis with CAE software
- DFM and DFA analysis
- Evaluation of materials selection



Concept Design

- Defining the intended purpose of the device based on user needs and clinical requirements
- Device functional diagrams, materials and technology options
- Market analysis, intellectual property studies and feasibility studies with technical and economic assessments
- Regulatory compliance and standards identification
- Design control and establishment of DHF



Risk Management

- Risk management plan
- Risk assessment FMEA
- Risk control
- Evaluation of overall risk acceptability
- Risk management report



Design Verification with Prototype

- Various prototyping options such as 3D printing, CNC, and silicone vacuum forming
- Functional tests and usability studies
- DFMEA review and design output
- Production and assembly process studies with PFMEA



Mold and Automation Fabrication

- High precision mold with minimum of 1 million shots with consistent quality
- Mold certification process to prove the molds are qualified and consistent
- Process validation with IQ, OQ and PQ



Excellence in Medical Device Contract Manufacturing



Molding Process

- ISO class 8 clean room injection molding
- Plastic injection molding, metal injection molding and liquid silicone molding
- Scientific injection molding and DOE application in process



Production with Automation

- Automation provides high production efficiency, accuracy, and safety



Post-production Process and Sterilization

- Manual assembly with well-trained and skilled workers
- Various printing solutions for products, such as pad printing
- EO and gamma radiation sterilization



Medical Device Regulatory

- EU MDR
- US FDA registered
- China NMPA registered
- Korea KFDA registered
- Quality system ISO 13485, QMSR 820
- Clean room standard ISO 14644



Quality Control

- Process Control Plan
- Incoming material inspection (IQ), Pre-production inspection, First article inspection (FAI), In-process inspection (IPQC), Final product inspection
- Continuous improvement with SPC methods and data collection



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满足药械需求的解决方案

Solutions for Drug Delivery Needs



产品工程

Product Engineering

- 使用 CAD 软件进行 3D 建模及机械结构设计
- 使用 CAE 软件进行公差分析和模流分析
- 可制造性与可组装性设计分析
- 材料评估



概念设计

Concept Design

- 医疗器械的预期用途定义基于用户和临床需求
- 医疗器械功能图、材料和技术选项
- 市场分析、知识产权研究和可行性研究，包括技术和经济评估
- 识别适用的法规和标准
- 设计控制和 DHF 历史档案



风险管理

Risk Management

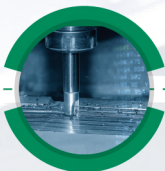
- 风险管理计划
- 风险评估 FMEA
- 风险控制
- 整体风险可接受性评估
- 风险管理报告



设计验证

Design Verification with Prototype

- 各种原型制作，如 3D 打印、CNC 加工和硅胶真空成型
- 功能测试和可用性研究
- 设计失效模式及影响分析评审及设计输出
- 生产和组装过程评估及生产失效模式及影响分析



模具与自动化制造

Mold and Automation Fabrication

- 高精度模具至少可达一百万啤，并保持稳定的品质
- 模具认证过程证明其模具合格且一致
- 过程确认，包括安装确认 (IQ)、运行确认 (OQ) 和性能确认 (PQ)



INNOVATION · PASSION · QUALITY

可靠的医疗器械开发及制造合作伙伴

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注塑成型

Molding Process

- ISO 8 级 (10万级) 洁净车间
- 塑料注射成型、金属注射成型和液体硅胶成型
- 科学注塑与DOE工艺应用



自动化的生产

Production with Automation

- 自动化提供了生产的高效率、准确性和安全性



生产加工与灭菌

Post-production Process and Sterilization

- 由受过良好训练且技术熟练的工人进行手动组装
- 产品的各种印刷方案，如移印
- 环氧乙烷及伽玛灭菌



医疗器械法规

Medical Device Regulatory

- 欧盟医疗器械法规 (EU MDR)
- 美国 FDA 注册
- 中国 NMPA 注册
- 韩国 KFDA 注册
- 质量体系 ISO 13485, QMSR 820
- 洁净车间标准 ISO 14644



品质控制

Quality Control

- 过程控制计划
- 来料检验 (IQC)、生产前检验、首件检验 (FAI)、生产过程检验 (IPQC)、成品检验
- 通过统计过程控制方法 (SPC) 和数据收集进行持续改进



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