statice

FULL ENGINEERING SERVICES
CONTRACT MANUFACTURING

Implants & Catheters
Active medical devices

Your Partner For Advanced Medical Devices

CONTRACT MANUFACTURING

From ramp up to full production, ***STATICE*** provides manufacturing services adapted to the customer's needs. Production management with ERP and MES ensures full traceability. All processes are controlled in cleanrooms class ISO 5 and ISO 7.

PURCHASE ORDER

SUPPLY AND SCHEDULING

MANUFACTURING

QUALITY CONTROL

CLEANING/ PACKAGING : ISO 5

LABELLING

RELEASE - READY TO BE STERILIZED : DHR, TRACEABILITY, COC

ERP / MES

FULL ENGINEERING SERVICES

Since 1978, ***STATICE*** provides engineering services and contract manufacturing. The company has gathered a strong know-how in process engineering and design transfer. The engineering department with 25 people has strong experience in the development of implants, catheters and active medical devices. The team works according to customer specification and proposes breakthrough technologies for bespoke solutions. ***STATICE*** has access to advanced technologies thanks to its internal research activity.

TECHNOLOGICAL RESEARCH

- Internal research activity
- European projects
- Biomaterial PhD

DESIGN & PRODUCT DEVELOPMENT

CLINICAL FIELDS : Neurology | Cardiology | Urology | Ophthalmology | Orthopaedics & others

DHF
Design
History
File

- Support for risk analysis & usability
- Specifications
- Investigation & justification of solutions
- Material selection
- Feasibility/Proof of concept: Early technical study, mock up, 3D printing, tests
- Mechanical and electronical design
- Software development
- Packaging design

- Prototyping
- In-house mechanical workshop (CNC, EDM) : components and tooling
- In-house electronic lab

- Respect of biocompatibility. (ISO 10993-1)
- Bench tests & validations in our laboratory
- Test reports

PROCESS ENGINEERING & DESIGN TRANSFER

DMR
Device
Master
Record

- Optimisation of manufacturing methods
- Process flowchart, work instructions, control instruction
- Packaging & labelling definition

ALL PARAMETERS IN ERP | **OPERATORS TRAINING** | **PILOT RUN**

VMP + REPORTS
- Verification & Validation (V&V) of product performance
- Qualification (IQ/OQ/PQ) of special processes
- Qualification of Cleaning and Packaging (ISO 11607)
- Software Validation (EN 62304)
- PFMEA

➡ **DESIGN TRANSFER APPROVAL**

IMPLANTS & CATHETERS EXPERTISE

TRANSFORMATION OF BIOCOMPATIBLE MATERIALS

- Liquid Silicone Rubber (LSR) injection
- Compression moulding with High Consistency Silicone
- Silicone over-moulding
- Silicone calendering (sheeting w/o polyester meshes)
- Silicone dipping
- Bioresorbable polymers injection (PLLA, PGA, PCL, PDO,...)
- Thermoplastics injection or over-moulding (PEEK, PUR, PE...)

INTEGRATION AND ASSEMBLY WITH

- Metallic parts (nitinol, platinum, titanium, stainless steel)
- Silicone parts
- Plastic parts
- Wires
- Ceramic
- Gold markers

ASSEMBLY TECHNOLOGIES

- Plasma treatment + gluing: silicon, UV, epoxy
- Welding: laser, ultrasound, electrical, high frequency
- Mechanical assembly:
  Clipsing, riveting, setting, forced bushing

INNOVATIVE AND TECHNICAL CATHETERS

- Endovascular electrophysiology
- Active catheters RF, microwave
- Disposable endoscopes
- Delivery systems
- Neuro / Neurovascular

WITH:

- Ergonomic handle
- Steering capacity
- Plasma treatment + technical coatings
- Sensors embedding (ablation electrode, P°, T°, $P°O_2$)
- Balloon & irrigation function (Multilumen tubes)

ELECTROSPINNING TECHNOLOGIES

Polymer fibers created by electrospinning are used for:

- Tissue regeneration features such as patches, vessels, valves, scaffolds.
- New mechanical behaviors: bioresorbable and non-bioresorbable polymers
- Controlled drug release

ACTIVE MEDICAL DEVICES AND IVD EXPERTISE

ACTIVE MEDICAL DEVICE

- Biomaterial interface with the body
- Integration of electronics
- Micromechnical systems (MEMS)
- Development of plastic housing
- Management of tightness
- Validation following IEC 60601
- Electromagnetical compatibility (EMC)
- Electrical safety

ELECTRONICAL DESIGN

- Digital and analog electronics
- Microprocessor embedding
- Thermal regulation (Hot or Cold)
- Engine drivers
- RF generator
- RF et NFC communication
- Bluetooth, WIFI

SOFTWARE

- Human Machine Interface (HMI)
- Database
- Embedded software (microprocessor)
- Traceability patient / product
- Development of applications on Windows, iOS, Android (tablet and PC)

IVD

- Precision fluids movement, microfluidic manifolds
- Micromechanical systems
- Automation
- Optic, Electromagnetism

Since 1978 ***STATICE*** is one of the European leaders in the subcontracting medical device industry. ***STATICE*** is a regular partner in French and European research projects and is recognized in Europe for its innovation skills. The company is certified ISO 13485.

www.statice.com

9 Rue Thomas Edison | 25000 Besançon
Phone: **+33 381 48 43 43** Fax : **+33 381 53 35 23**
commercial@statice.com

statice

statice

REGULATORY AFFAIRS FOR INNOVATIVE MEDICAL DEVICES

Your Partner For Advanced Medical Devices

REGULATORY STRATEGY

Evaluate and define the different regulatory options to optimize the market access (European and International)

- Definition of the regulatory class of the device
- Recommendations for regulatory approaches and strategic impacts
- Identification of the actions to be carried out and guidance in their implementation

PREPARATION OF THE TECHNICAL DOCUMENTATION

Provide you with the valuable keys to CE marking and international certification

- Draft or assistance for the technical / certification file
- Support for the international registration of your products
- Support in the selection and management of the relationship with notified bodies and/or authorities

VALIDATION

Provide you with complete pre-clinical data records such as

- Biological assessment file
- Usability file
- Sterilization validation file (including microbiological data)
- Software validation file
- Validation file for special processes (moulding, gluing, cleaning, packaging, …)
- Electrical validation file (EMC / electrical safety)

DEPLOYING AND IMPROVING YOUR QMS

In support or complete realization

- Implementation of a QMS (ISO 13485, 21CFR Part820, ...) or optimization of your own QMS
- Setting up your postmarketing requirements
- Support in communication with notified bodies and/or authorities

Contact :

Sébastien PERROT
+33 381 48 48 87
s.perrot@statice.com

Élise WALLART
+33 381 48 43 43
e.wallart@statice.com