statice

Innovative Medical Solutions

R&D | V&V | RA | CONTRACT MANUFACTURING

IMPLANTS | CATHETERS | ACTIVE MEDICAL DEVICES | SINGLE USE DEVICES

Contract Design & Manufacturing Organisation

ISO 13485

R&D V&V RA

Turning your requirements into innovative medical device

An **experienced, skilled and multidisciplinary** team drives the development of your medical device, combining creativity and **responsiveness.**

Our **experts** deliver end-to-end support for the development of medical devices up to **Class III.**

At the outset of the project, STATICE assesses **relevant standards** to your medical device, ensuring compliance with critical regulatory requirements such as **risk management** (ISO 14971) and **biocompatibility** (ISO 10993).

STATICE assists across **all key development stages** of your medical device:

- Requirements / Specifications definition
- CAD / Material selection / Numerical analysis
- Proof of concept
- Prototyping
- Tooling manufacturing
- Verification and validation
- First-in-human batch manufacturing

R&D

- Microtechnology
- Polymers
- Electronics (IEC 60601, EN 45502)
- Software (IEC 62304)

INDUSTRIALISATION

- Device Master Record (Manufacturing plan, work instructions)
- Label definition (ISO 15223)
- Production tools development
- Ramp-up management

VALIDATIONS

- Product performances
- Molding IQ/OQ/PQ
- Cleaning (ISO 19227)
- Packaging (ISO 11607)
- Software (IEC 62304)
- Sterilization (ISO 11335)

RA

- Regulatory strategy
- Biological assessment (ISO 10993)
- Technical file preparation
- QMS implementation (ISO 13485, 21 CFR Part 820)

CONTRACT MANUFACTURING

Controlled production of your medical devices ready for sterilization

STATICE operates two production sites: one located in ↗ Besançon (France) and the other in ↗ Mauritius.

High capacity production facilities compliant with regulatory requirements **(ISO 13485) :**

- Four **ISO7** cleanrooms, totalling **900 m²**,
- A **200 m²** workshop dedicated to **mechatronic assembly.**

From components sourcing to the delivery of products ready for sterilization**, STATICE manages the entire supply chain.**

Efficient physical flow management:

- A **300 m²** incoming reception, inspection and **storage area** spread over two levels,
- A **dedicated shipping zone** for dispatch to the sterilization partner or directly to the final customer.

Information flows are controlled via our **ERP** system, guaranteeing end-to-end **traceability** of manufactured devices (Device History Record).

Annual production volumes range from **small batches to high-volume series.**

INNOVATIONS

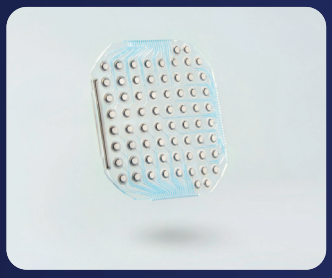
cardiology

neurology

urology

orthopaedics

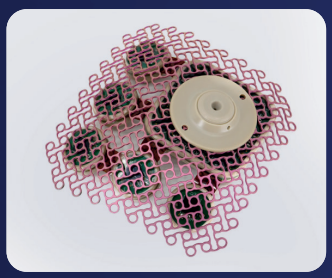
ophthalmology



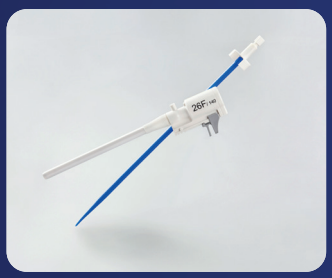
Brain computer interface implant

Steerable catheter for electrophysiology & ablation procedures

Penile implant

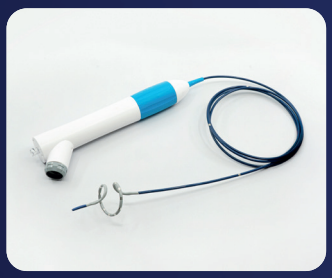


Brain ultra sound implant



High quality sealing vascular introducer

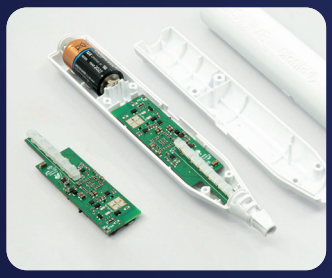
Artificial urinary sphincter



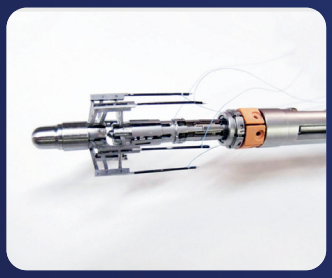
Nerve stimulation catheter

Electroporation device

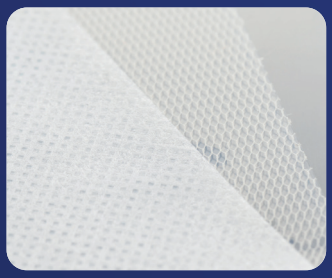
Silicone-Metal implant



Catheter handle with embedded electronics and software



Suturing device



Silicone sheeting with Dacron® reinforcement

TECH CAPABILITIES

STATICE has brought many key manufacturing processes in-house, ensuring independence, safety, and strong responsiveness

- **Silicone** (HCR / LSR) parts manufacturing by molding, calendering or dipping processes
- Thermoplastic injection molding or overmolding (PEEK, PUR, PEBAX, SANTOPRENE, PC, ABS,...)
- Bioresorbable parts molding (PLLA, PLAGA, PDO, PCL)

- Assembly process :
  - → UV glueing / Epoxy glueing
  - → Plasma surface treatment
  - → **Catheter tipping**
  - → **Catheter assembly** by welding process
  - → **Laser welding**
  - → Electrical welding

- **Electronic process** :
  - → PCB manufacturing and wiring
  - → PCB epoxy potting

- Laser engraving
- **Cleaning process** (ultrasonic bath / washer-disinfectors)
- **Packaging** for sterilized medical devices (Tyvek bag & blister)
- Labeling / **UDI management**

Industrial Expertise

More than 45 years of proven experience in developing and manufacturing medical devices

Reliable Timelines / Responsiveness

Internalized Processes skilled team

Flexibility

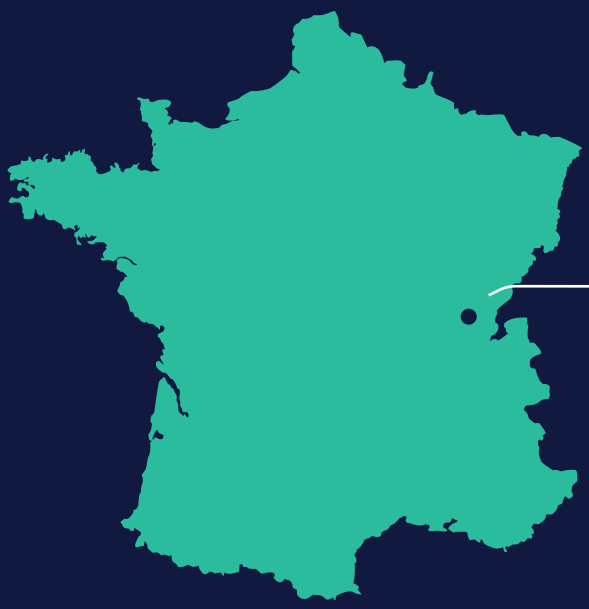
A variety of processes tailored to your needs, supported by a multidisciplinary team

Compliance

Process validation – Regulatory requirements integrated from project initiation

SINCE 1978

STATICE, your partner for customized development
and production of your medical devices



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statice
Innovative Medical Solutions

Full QARA services for your innovative medical device class I to III

REGULATORY AFFAIRS | VALIDATIONS | QUALITY ASSURANCE | TRAINING

IMPLANTS | CATHETERS | ACTIVE MEDICAL DEVICES | SINGLE USE DEVICES

STATICE, your seasoned partner from the early needs expression to market clearance

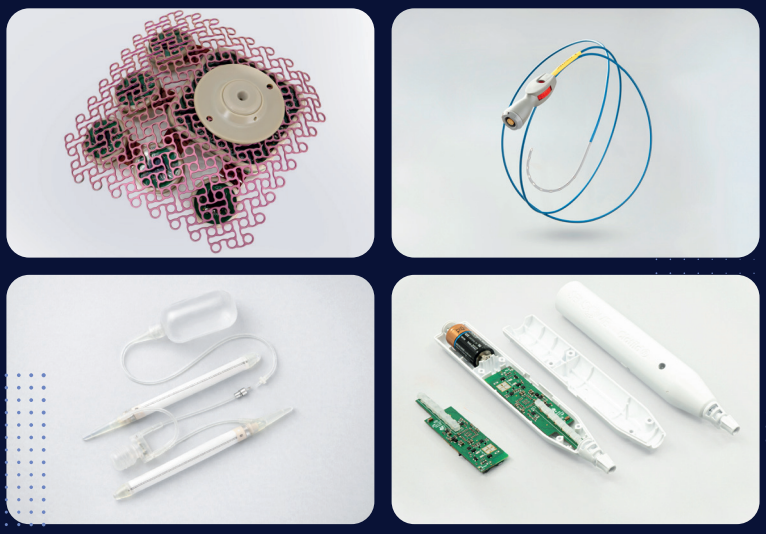
Regulatory Affairs

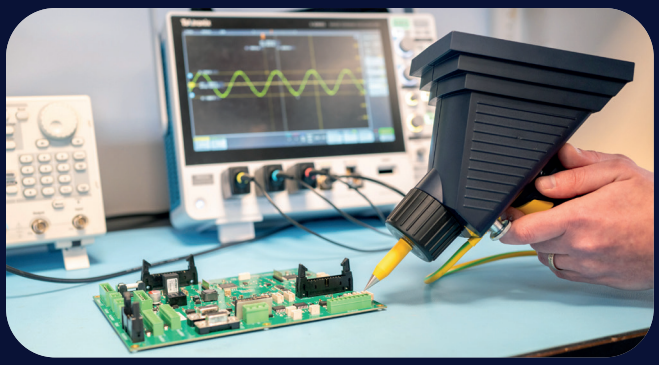
Regulatory strategy :

- Identifying and assessing all regulatory options in order to optimize 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

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

- Drafting of the technical file and submission
- Support for the international registration of your products
- Support in the Notified Bodies selection
- Relationship management with notified bodies and/or competent authorities





Verification & Validation

- Drafting of protocols and reports
- Mechanical or Physical tests after aging
- Electrical validation file (IEC60601)
- Usability (IEC62366)
- Software validation (IEC62340)
- Special processes validation :
  - → Cleaning - (ISO19227)
  - → Packaging - (ISO11607)
  - → Others : molding, gluing
- Sterilization validation (ISO11135/11137)
- Biocompatibility (ISO10993)

Quality Assurance :

- Set up of your Quality Management Sytem (compliance with ISO13485 & 21 CFR Part 820)
- Improvement of your Quality Management System
- Set up of your postmarket requirements
- Support in communication with notified bodies and/or authorities
- Running audits and support during audits

Training on-site or remotely about :

- Quality Management System topics
- Regulatory Affairs topics
- Specific standards

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