



## GLOBAL PARTNER FOR YOUR MEDICAL DEVICE

- R&D
- VERIFICATION & VALIDATION
- INDUSTRIALISATION
- MANUFACTURING
- QA / RA



### Contact

Julien Gauthier

+33 (0)6 80 00 47 34

[jgauthier@cisteomedical.com](mailto:jgauthier@cisteomedical.com)

### More Information

[www.cisteomedical.com](http://www.cisteomedical.com)

# Presentation

## Our mission

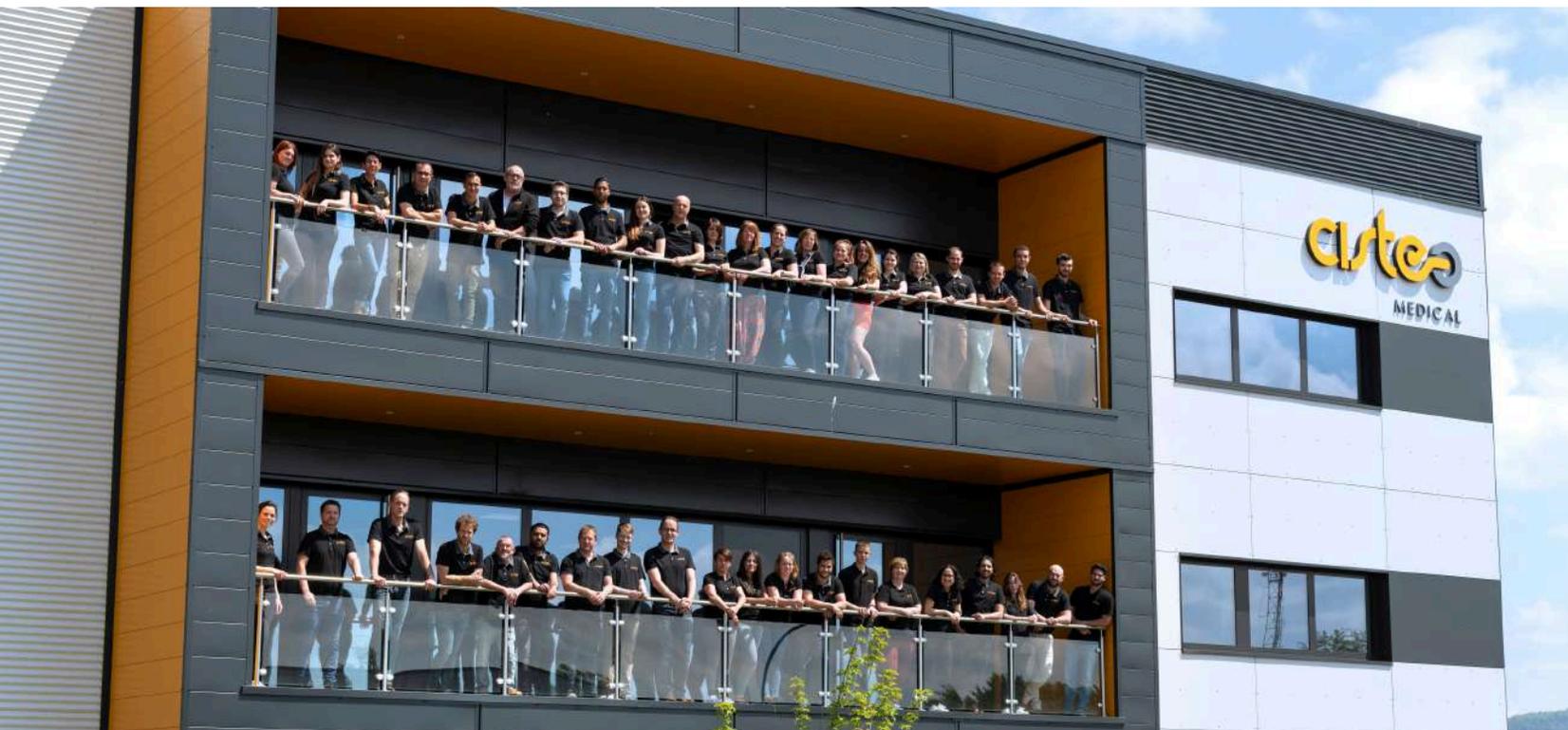
Cisteo MEDICAL supports, project leaders, start-ups and medical device manufacturers in their **design, development, approval**, and **manufacturing** through their micro technical and regulatory expertise, under contract.

## Our purpose

Contributing to the health of tomorrow through medical devices.

## Our values

**Innovation**  
**Satisfaction**      **Expertise**  
                                 **Responsibility**  
                                 **Collective work**  
**Efficiency**  
**Transparency**



### Contact

Julien Gauthier

+33 (0)6 80 00 47 34

[jgauthier@cisteomedical.com](mailto:jgauthier@cisteomedical.com)

### More Information

[www.cisteomedical.com](http://www.cisteomedical.com)

# Presentation

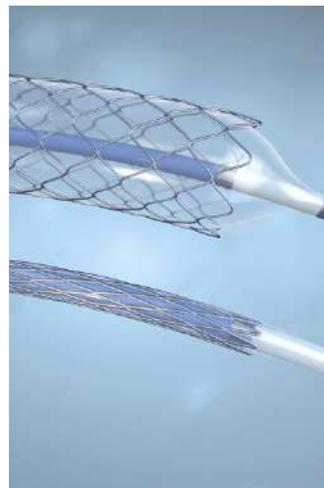
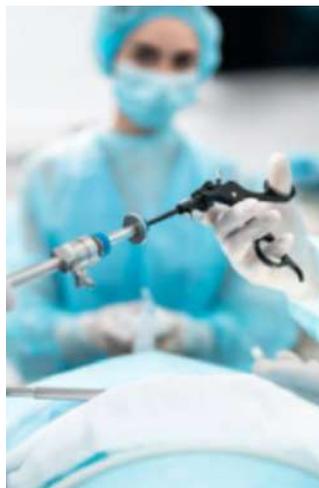
## Our offer

Cisteo MEDICAL supports you **from the product definition phase to the serial manufacture** of your medical device with the ability to perform the following steps, according to the applicable standards:

- Conception
- Design for prototyping
- Proof of concept
- Mock-ups and test bench
- Prototype
- Design for manufacturing
- Functional Prototype
- Pre-series used for V&V
- Industrialisation
- Series

## An Expertise in high-criticality medical devices

- Active implantable medical device (AIMD)
- Implant, specifically shaped stent, balloon
- Surgical instrumentation (catheter,...)
- Surgical Robotics
- Electro-medical devices



### Contact

Julien Gauthier

+33 (0)6 80 00 47 34

[jgauthier@cisteomedical.com](mailto:jgauthier@cisteomedical.com)

### More Information

[www.cisteomedical.com](http://www.cisteomedical.com)

## A methodology dedicated to medical requirements

As a **critical subcontractor**, Cisteo MEDICAL has set up a design process enabling to integrate the deliverables expected during the **constitution of the technical file** from the outset.

Our work is based on the following standards:

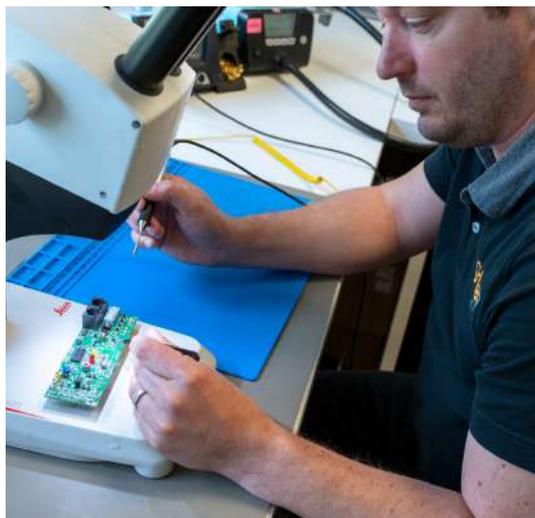
- MDR 2017/745 Regulation
- ISO 13485 : 2016
- 21 CFR Part 820
- IEC 62304
- NF EN 60601-1 and collateral standards

We also strive to implement good design practices, based particularly on risk analysis (design for risk).

## A single provider at the service of your medical device



MICROMECHANICS



ELECTRONICS



SOFTWARE



### Contact

Julien Gauthier

+33 (0)6 80 00 47 34

[jgauthier@cisteomedical.com](mailto:jgauthier@cisteomedical.com)

### More Information

[www.cisteomedical.com](http://www.cisteomedical.com)

# R&D Micromechanics



## Benefits

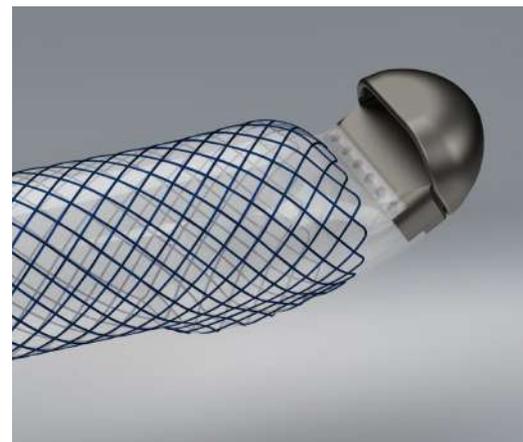
- Mastery of ISO 13485
- Expertise in innovative devices
- Micromechanical knowledge adapted to **minimally invasive surgery** but also to **robotics** (gain in precision and comfort)



## Development in micromechanics

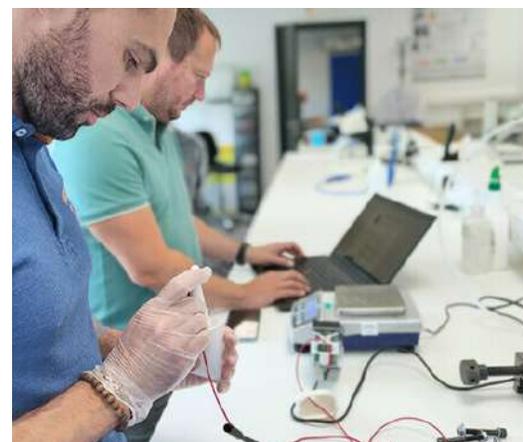
### SKILLS

- Support for patent deposit
- Formalisation of technical specifications based on user requirements
- Research and development
  - **Development of innovative solutions** based on specifications or on customer's requirements in compliance with medical standards
  - **Analysis of an existing design for design optimisation**
  - **Search for solutions** to remove technical barriers
  - **Design of the device and its associated instrumentation**
- 3D Modelling
- Numerical simulation by finite element method (estimation of the strength of materials)
- Realistic rendering
- Prototyping
- Design and manufacturing of test benches
- Bench functional tests
- Test report



### SOME EXAMPLES

- Integration of a drug delivery channel to an articulated laparoscopy forceps
- Development of a Class III device for the repair of mitral valve and its instrumentation
- Development of operated instrument holders incorporating a sterile field for surgical robots



### Contact

Julien Gauthier

+33 (0)6 80 00 47 34

[jgauthier@cisteomedical.com](mailto:jgauthier@cisteomedical.com)

### More Information

[www.cisteomedical.com](http://www.cisteomedical.com)

# R&D Electronics and Software



## Benefits

- Services provided according to applicable standards: MDR 2017/745, IEC 62304, standards 60601 (series)
- R&D laboratory for a quick transition to the mock-up phase
- A single subcontractor: Integration of electronic sub-assemblies by the micromechanics department and collaboration between teams
- From design to series production of the device

## Electronic development



### SKILLS

- Design of multilayer electronic boards
- Implementation of microcontrollers
- Wireless communication (Bluetooth, ...)
- Battery and charging management
- Sensor signal acquisition
- Motor control
- Electronic and mechanical co-design ECAD/MCAD
- Mechatronic design of test benches

### EXAMPLES

- Development, design, electronic sensor management boards for hydraulic and pneumatic circuits

## Software Development



### SKILLS

- Development process according to **IEC 62304**
  - Design
  - Documentation
  - Testing and validation
  - Maintenance
- Software development (PC, smartphone, tablet,...)
- Embedded software development (microcontroller, FPGA, IOT)
- HMI integration according to customer graphic charter
- Software development for test bench

### EXAMPLES

- Development of the management firmware of a class IIa medical electrical device
- Development of test benches allowing in-process controls
- Automation of release sheets



## Contact

Julien Gauthier

+33 (0)6 80 00 47 34

[jgauthier@cisteomedical.com](mailto:jgauthier@cisteomedical.com)

## More Information

[www.cisteomedical.com](http://www.cisteomedical.com)

# Verification & Validation

## Design verification

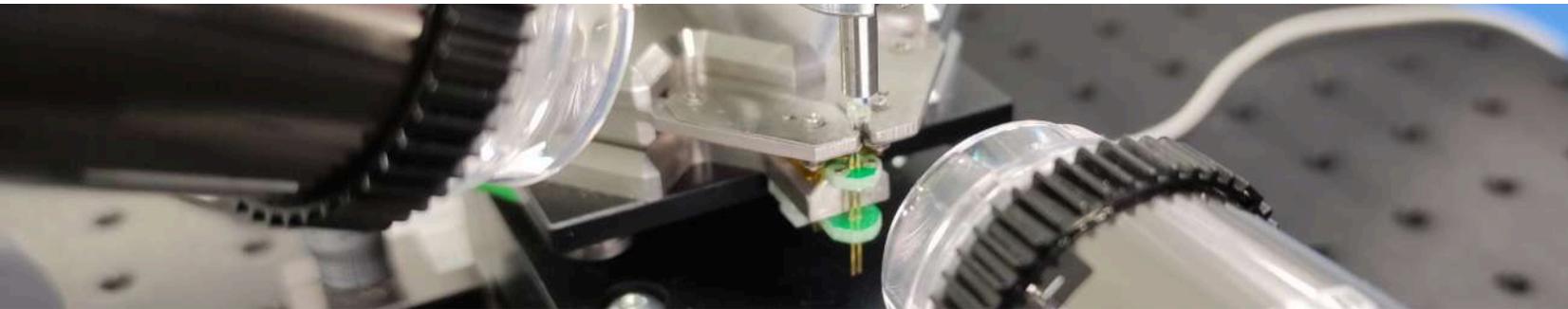
Cisteo MEDICAL support you with your design verification phases, mainly for:

- Drawing up protocols
- Carrying out tests and test reports
- Design and manufacture of customised test benches

## Design validation

Cisteo MEDICAL is able to manufacture devices for the validation phases by ensuring mainly:

- Drawing up the manufacturing file
- Supplier qualification
- Process validation
- Environmental control



### Contact

Julien Gauthier

+33 (0)6 80 00 47 34

[jgauthier@cisteomedical.com](mailto:jgauthier@cisteomedical.com)

### More Information

[www.cisteomedical.com](http://www.cisteomedical.com)

# Industrialisation

## Transfer to production

Cisteo MEDICAL not only manufactures small series, but also takes care of the production start-up stage in order to guarantee the delivery of larger volumes, essentially by **implementing suitable and repeatable processes**.

This stage involves research into processes that are compatible with mass production, the organisation of the flows, the design and production of tooling.

We also integrate existing production processes as part of dual sourcing or when switching to an ISO13485 subcontractor.

## Validation and Manufacturing Record (DMR)

Following the drafting of the customer requirements matrix and the process risk analysis, Cisteo MEDICAL implements:

- Validation of processes by test batches and IQ/OQ/PQ
- Implementation of the manufacturing file (DMR) including:
  - Selection and qualification of suppliers
  - Bill of materials, manufacturing, and inspection instructions
  - Tooling and equipment maintenance plan

## Continuous improvement

Cisteo MEDICAL supports you during the production ramp-up phases. By technical and quality constraints study, we adapt the ramp-up to optimise manufacturing costs.



### Contact

Julien Gauthier

+33 (0)6 80 00 47 34

[jgauthier@cisteomedical.com](mailto:jgauthier@cisteomedical.com)

### More Information

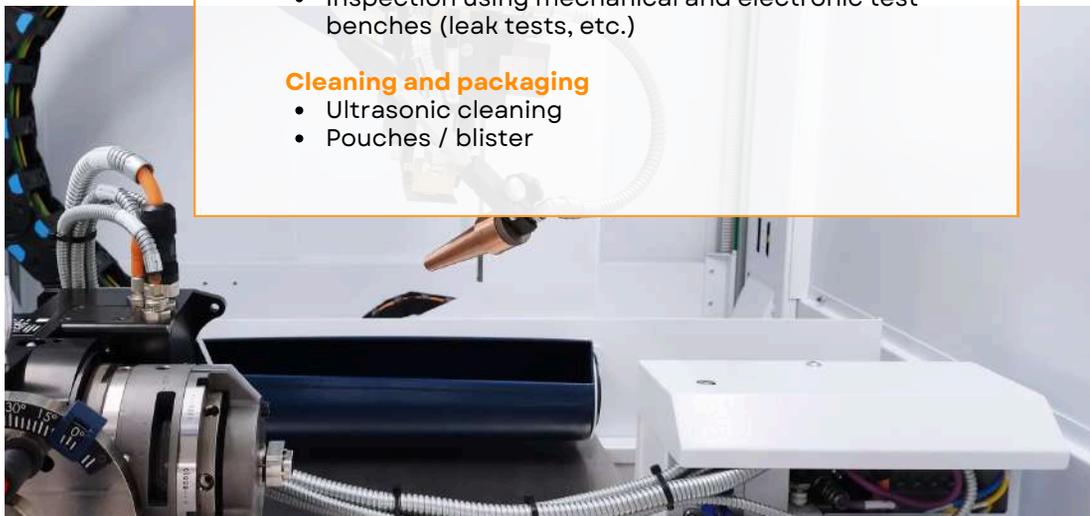
[www.cisteomedical.com](http://www.cisteomedical.com)

# Manufacturing

## Clean room processes

Cisteo MEDICAL has a clean room environment of 250 m<sup>2</sup> enabling the manufacture and assembly of highly technical devices.

Our cleanrooms (ISO 5 and ISO 7) incorporate several **innovative processes**, allowing us to provide **tailor-made services** according to your needs.



### Silicone Processing

- Over moulding
- Injection
- Spraying
- Dipping
- Assembly by silicone gluing
- Silicone colouring
- Marking on silicone
- Polishing

### Epoxy resin casting

- Over moulding
- Encapsulation

### Welding

- 5-axis laser in a clean room
- Resistive welding on ESD table
- High-frequency welding
- Leak testing

### Marking

- Silicone deposition
- Laser marking in clean room (logo, batch and serial number, QR code)
- Management of serial numbers and UDI

### Heat Treatment

- NITINOL shaping by heat treatment
- Plastic components shaping by heat treatment

### Surface activation

- Plasma

### Polishing

- Optical fiber
- Silicone

### Assembly

- Mounting and electronic board assembly
- Connectors
- Micro-assembly by gluing
- Micromechanical assembly
- Inspection using mechanical and electronic test benches (leak tests, etc.)

### Cleaning and packaging

- Ultrasonic cleaning
- Pouches / blister



## Contact

Julien Gauthier

+33 (0)6 80 00 47 34

[jgauthier@cisteomedical.com](mailto:jgauthier@cisteomedical.com)

## More Information

[www.cisteomedical.com](http://www.cisteomedical.com)

# Quality and Regulatory Affairs

## Internal Audit

Cisteo MEDICAL can provide audit support, whether it's for an inventory of fixtures or prior to submission to a notified body.

As an ICA-certified auditor, we work on:

- QMS audit in accordance with ISO 13485 (manufacturer and subcontractor) and 21CFR Part 820
- Audit of technical documentation in accordance with MDR2017/745

## Quality Support

Cisteo MEDICAL support you in **setting up or maintaining your quality management system** with a view to certification to **ISO 13485: 2016 and/or 21 CFR Part 820**.

## Regulatory Support

Cisteo MEDICAL can help you with your regulatory procedures:

- Definition of the marketing strategy for your device
- **Drafting of all or part of your technical** file in accordance with MDR 2017/745 and 21CFR Part 820
- Support in responding to your notified body or competent authorities

## Hotline DM

Hotline DM is a service that gives you a quick, relevant answer to your regulatory and quality questions, as well as the opportunity **to talk directly to a member of the regulatory team**.

The service operates on a time credit basis.



Two members of our team are listed as **expert advisers** by BPI France for the Diag DM scheme, which provides **50% funding** for regulatory and quality services..



### Contact

Julien Gauthier

+33 (0)6 80 00 47 34

[jgauthier@cisteomedical.com](mailto:jgauthier@cisteomedical.com)

### More Information

[www.cisteomedical.com](http://www.cisteomedical.com)

# Quality and Regulatory Affairs

## Training

Cisteo MEDICAL is a **Qualiopi-certified training centre**.

We offer a catalogue of training courses tailored to medical device manufacturers and their subcontractors.

- Quality management system - ISO 13485:2016
- Technical documentation - MDR 2017/745
- Biological risk assessment - ISO 10993-1
- Clinical evaluation of medical devices - MEDDEV 2.7/1 rev4
- Toxicological analysis - ISO 10993-17
- Risk analysis - ISO 14971
- Post-Market Surveillance (PMS)
- Cleanrooms and related controlled environments - ISO 14644
- Internal audit / Supplier audit - ISO 19011
- Suitability for use - IEC 62366-1
- Regulatory and standards watch

Tailor-made training courses can be created specifically to meet your needs.



### Contact

Julien Gauthier

+33 (0)6 80 00 47 34

[jgauthier@cisteomedical.com](mailto:jgauthier@cisteomedical.com)

### More Information

[www.cisteomedical.com](http://www.cisteomedical.com)



### **Contact**

Julien Gauthier

+33 (0)6 80 00 47 34

[jgauthier@cisteomedical.com](mailto:jgauthier@cisteomedical.com)

### **Cisteo MEDICAL**

1 Rue Anne de Pardieu

F - 25000 Besançon

### **More Information**

[www.cisteomedical.com](http://www.cisteomedical.com)