



innov'Health


Health Industry Competitiveness Cluster

BURGUNDY-FRANCHE-COMTÉ

Know-How and Skills of Burgundy-Franche-Comté Healthcare companies

21 examples of companies' excellence -
Innov'Health Cluster members





La
FRENCH TECH

Innov'Health Cluster runs the French Tech dynamic, member of the Health Tech thematic network, which represents biotechs, medtechs and e-health companies in the Burgundy-Franche-Comté region

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Editorial

Innov'Health Cluster was born of the Pôle des Microtechniques (Micro-technology Cluster) to clearly display his strong position in the Healthcare sector. It represents the continuation of the Healthcare group of expertise that has been existing for more than 10 years in Besançon.

The ambition of the Healthcare sector manufacturers is to gather and to carry out collective actions in order to reduce costs and be more efficient thanks to a strong networking effect.

Cluster members meet regularly to review the progress of ongoing work and enable each new member to present itself in the Burgundy-Franche-Comté region. Collective actions, including attending specialised trade shows (MedFIT, Compamed...) also achieve this collaborative work.

Innov'Health has partnerships with numerous events (Hacking Health, Rentrée du DM...) and often joins other clusters (IVAM in Germany, Enterprise Ireland...) in order to promote the local industrial ecosystem as well as its skills.

Florent GUYON
Innov'Health Cluster President

We are proud to represent the Healthcare sector in the Burgundy-Franche-Comté region and this leaflet is a first impression of our outstanding know-how and skills in the region, via some selected examples.

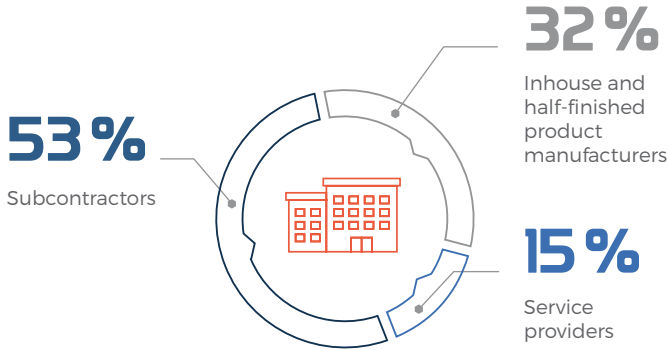
The Healthcare activity sector is one of the strongest axis that the Pôle des Microtechniques members wanted to develop through the Burgundy-Franche-Comté cluster, Innov'Health.

Innov'Health provides the region and companies with visibility which participates to that collective dynamic. It offers a wide range of services related to business and skills development.
The cluster is open to companies and Healthcare actors, come join us...

Étienne BOYER
Pôle des Microtechniques President

REGIONAL KEY FACTS AND FIGURES OF THE HEALTH SECTOR

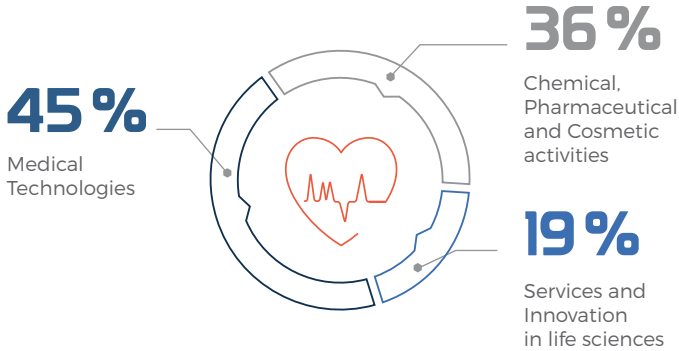
Companies Classification



Medical Technologies

- Medical Devices (including implantable and active ones)
- Diagnosis (including biology and imaging equipment)
- Telemedicine software...

Burgundy-Franche-Comté Business Sectors



Chemical, pharmaceutical and cosmetic activities

- Originator and generic drugs
- Cosmetic and hygiene products
- Veterinary drugs...

Services and innovation in life sciences

- Clinical research
- Tests, analysis and quality control
- Cleaning and sterilisation...

A Rich Ecosystem

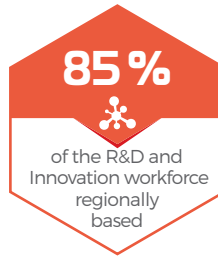
Large companies



World class research and clinical centres



THE HEALTH CARE SECTOR REPRESENTS



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MEDTECH / BIOTECH /
PHARMA



Design, Development, Project management... Services dedicated to make a start on your Innovative Medical Device whatever your medical speciality is.



Certifications 2018:
NF EN ISO 13485: 2016

Design, development and project management are 1Bu2 Innovative R&D strengths dedicated to Innovative Medical Devices.

1Bu2IRD brings to its clients (manufacturers, practitioners, and research laboratories) a wide range of customised services, from ideas to commercialisation of innovative products.

Global overview of some offered services:

- **ideas:** translation of the concept idea expressed by the client, related to his needs
- **pre-study:** technical and economic feasibility analysis of the concept
- **specification:** listing of the product and client's needs specifications
- **design:** product creation from the idea, according to the specification and integrating applicable standard requirements. Work performed by means of SolidWorks
- **prototyping:** physical draft of the product designed.
- **Full R&D phase:** includes all stages from pre-study to prototyping
- **additional services:** design, **packaging, labelling**, and **instruction manual** of the product, taking into account sterilisation and materials specifications as listed with our client within the specification
- **project management:** from the idea to the commercialisation of the product. For the post-design stages, 1Bu2IRD provides the strength and quality of its network of subcontractors

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Each step of the project is led in accordance with the specification and the applicable standard requirements related to our activity sector.



HEALTH / MEDICAL
DEVICE



Your partner from idea to medical market

You have an idea, a concept, a patent, a prototype... Alcis offers you its expertise and equipment to help you achieve your project and have a **certified medical device, ready to be marketed.**

Alcis has more than **25 years-experience** in the medical device sector and can provide you with a product CE marked, from **class I** to **class III**. Alcis fosters your activity launch and your product development. We can also set up your quality management system and assume the role of legal manufacturer.

We can manufacture your medical devices within a controlled atmosphere (clean room of class ISO 5 & 7), as OEM or simply offer you CE marked medical devices, ready for sale and use.

Alcis's global overview enables a better management of projects on the development and certification of medical devices.

Alcis strength: a business on a human scale, a strong complementarity between its services (regulation, studies and manufacturing).



Certifications:

NF EN ISO 13485: 2003 & 2012



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IN VITRO DIAGNOSTIC /
MEDICAL DEVICE



Development of products and mechatronics specialised machines

ALCYM provides mechatronics products development, according to specifications brought by its clients, including **prototyping**, **verification** and **production**. ALCYM expertises are especially focused on mechanics, electronics, computing and microfluidics.

ALCYM has the Research Tax Credit accreditation that can recover benefits on all its R&D Services.

ALCYM service example:

In partnership with Biomérieux, a world leader in the field of in vitro diagnostics, ALCYM developed a diagnostic robot which is able to prepare samples in order to accelerate microbial cultures detection into the blood.

The robot makes it possible to analyse 12 blood samples simultaneously. The overall protocol duration is approximately 12 minutes. Blood is introduced on a strip and lysis is performed, as well as microbe filtration on a special substrate.

Microbes are washed and transferred buffering on a microplate whose temperature is regulated. A reagent micro drop is then added, the quantity of microbes is controlled by the way of cameras for reading.

The card is then assessed by the client's mass spectrometer.



Certifications:
NF EN ISO 13485:
(in progress)



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HEALTH / MEDICAL
DEVICE



AOPB, the customised plastic injection

AOPB is a plastic injection specialised company located near Besançon.

Beside its plastic injection expertise, AOPB's special feature is its ability to internally design and manufacture moulds.

AOPB also extends its know-how to plastic parts decoration.

The gathering of these expertise related to plastic injection fosters **project monitoring** for its clients and reduces to only one supplier the scope of responsibility.

AOPB is a source of proposals on its know-how in order to support its client's projects according to the ISO 13485 standard.

AOPB is ISO 13485 certified for medical devices components on the following sectors of activity:

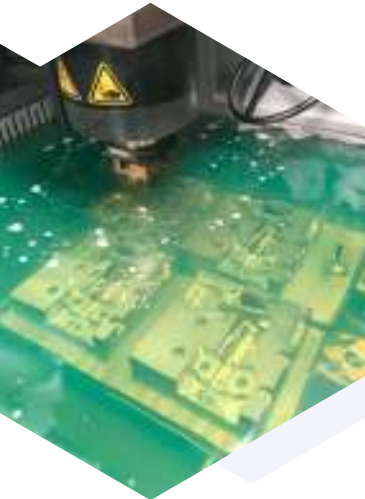
- moulds design and manufacturing
- plastic injection
- overmoulding
- medical devices components decoration

AOPB is also known in plastic injection to **manufacture** with existing moulds.

AOPB also performs **adjustments** and changes on existing moulds.



Certifications:
NF EN ISO 9001
NF EN ISO 13485



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HEALTH /
BIOTECHNOLOGIES



Bioexigence supports the dermo-cosmetics sector to promote their actives and/or their finished products (cream, patch...)

Thanks to its unique device, the **GlasBoxPlus®**, Bioexigence offers customised services in order to promote the efficiency of actives and finished products from the dermo-cosmetics sector.

Demonstrating the anti-aging effect of a product via several aspects:

- tightening effect on mature skin
- anti-wrinkle specific effects
- protective effect against harmful effects of exposure to blue light (computer and smartphone screens)
- protective effect against photoaging (UVA irradiation)

GlasBoxPlus® **examines skin mechanical properties** associated to the contractile functions of dermis cells (fibroblasts).

This device is able to follow the evolution of fibroblasts contractile functions in the presence of a reagent or a cream for 24 hours.

GlasBoxPlus® benefits:

It provides us with information on whether the cosmetic ingredients have a constant effect over 24 hours or whether it is mandatory to schedule a second application in order to maintain the effect over 24 hours.

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Biomane supports screening laboratories for high speed analysis of various diseases, including sickle cell disease

On the cutting edge of innovation, **Biomane** provides a real disruptive technology that facilitates the operation of biomarkers for screening and diagnosis of various conditions, thanks to:

- simplification and automation of innovative tools for target proteins' capture
- simplification and democratisation of the use of advanced technology proteins' analysers
- simplification and interpretation of results thanks to efficient IT tools

So as to:

- improve the specificity and sensibility of blood tests for better cares
- automate the analysis process for a greater traceability
- increase the analytical rate
- decrease the analysis costs

Biomane is based on a generic concept of **proteins' capture and characterisation** along with **automated methods of interpreting the results**, which allows its application to all health sectors.

The **first target application is high speed neonatal screening and diagnosis of sickle cell disease** (more than 1000 tests/day). With time, all other detectable diseases by means of proteins analysis are targeted.

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HEALTH /
PRE-CLINICAL TRIALS



Projects support and management in pre-clinical stage

Biossan runs a zootechnical experimental platform in which **research trials are driven on big animals in controlled conditions**. Biossan offers customised services in order to respond to each project specificity.

Biossan service example:

A company wants to validate a medical device that operates on the **digestive tract**. To do so, this company seeks Biossan expertise, which is able to achieve trials on pigs, whose model is the most closely related to human's one.

In such case, the needs are the following:

- **housing capacity** above 2 months
- **technical follow-up** achievement (urine test, blood sample, body weight follow-up, blood sugar, gastroscopy, radiography...)
- **operating room** made available for the device exposure and extraction with a veterinary from Biossan company (for the anaesthesia)

Biossan submits its **protocol** to the Ministry of Higher Education and to the local **ethics** committee.

Areas of expertise :

- medical device
- nutri-health
- surgery

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HEALTH / MEDICAL
DEVICE



European expert in Medical Devices Marking

Créatemps is one of the European leaders of printing on medical devices—implantable or not—on all types of materials including silicones, polymers, elastomers, metals and technical textiles.

Our workshop controls all the marking techniques: pad printing, screen printing, laser engraving, micro-dosing.

Our R&D department supports you in the development phase of your innovative projects, and provides a marking solution in compliance with your specifications, as for instance non-invasive laser engraving, USP class VI ink marking, high mechanical and chemical marking resistance, radiopaque, conductive, insulating...

All our works can be done in our clean room of class ISO 5.

In the progress of ISO 13485 certification (mid 2018), we already can support you in the IQ-OQ-PQ qualifications of the products you entrust to us.



Certifications:
ISO 13485 in progress



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HEALTH / MEDICAL
DEVICE

Cryla

Support and project management for minimally invasive medical devices



Certifications:
NF EN ISO 9001: 2008
NF EN ISO 13485: 2003

Cryla is a company that brings to its clients its expertise in **high precision** and **small dimensions**, which represents key skills within the medical device industry.

Cryla Service example:

A company contacts Cryla in order to manufacture a **plastic injection-moulded** part, with strong constraints on the used material. Cryla supports the company from the solution search phase and prototype **development**, to **assembly** of subassemblies, while offering practical solutions of **optimisation**, control of production costs and industrialization improvement. Complementary solutions are thus provided **including precision machining, fine cutting, mass finishing** and **welding**.

Cryla invested in 2017 in a **clean room of class ISO7 & ISO5** to support a start-up for production of small and medium-size series.

Cryla is able to work on all types of materials: metals (titanium, 316L stainless steel, Inconel, gold, silver, etc.), medical polymers (PEEK, polypro, SEBS, etc.).

Some Medical Device examples:

- various implants
- surgical instruments
- dental / Hearing components...
- analysis machines components

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HEALTH / MEDICAL
DEVICE



Precision Bar-turner, Manufactures class III IMD components for 30 years



Certifications:

NF EN ISO 9001: 2015

NF EN ISO 13485: (in progress)



DDLG is a family SME founded in 1948 that has been developing a strong know-how in watchmaking and naturally shifted into the medical sector 30 years ago.

DDLG supports its clients on the whole design and manufacturing process of **Implantable Medical Devices (IMD)**:

- **design**: study, detailed analysis of needs constraints, plan layout.
In that respect, DDLG can support Bpifrance sponsored **research projects** as pilot or partner.
- **production**: machining, polishing, micro blasting, assembly.
DDLG is able to manufacture technical and **complex** parts, as implantable chamber components and accessories, thanks to its expertise in biocompatible materials (including titanium, PEEK, and stainless steel).
- **quality control**: visual and dimensional controls analysis and reports.
DDLG places particular emphasis on quality system and components **traceability**.

DDLG works directly with regulatory manufacturers (CE marking and FDA approved product labelling).

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HEALTH / MEDICAL
DEVICE



Development, manufacturing and marketing of medical devices for neurosurgery



Certifications:
NF EN ISO 13485: 2012
ISO 13485: 2003
Brazil GMP

With more than 40 years-experience in development and production of **intracranial electrodes**, DIXI Medical has the necessary skills and means to develop, from **study to market**, applications in neurology and neurosurgery fields.

- A team composed of research and biomedical engineers in charge of development, technical follow-up, **validation** (risk management, biocompatibility, ability to use...) and medical devices **homologation**; team completed by a neurosurgeon consultant who brings his **medical expertise**.
- A production/manufacturing environment in **clean room** of class ISO7 & ISO5 and operators trained for the microtechnology assembling.
- **Specific equipment:**
 - UVA process system
 - electrical micro-welders
 - marking laser
 - computerised test rigs
 - medical packaging sealers

Commercial scope: Europe, Canada, Argentina, Brazil, Australia, Columbia, India.

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HEALTH / MEDICAL
DEVICE



Design and production of ultrasonic transducers for monitoring, imaging and therapy

Imasonic designs and manufactures high performance custom design ultrasound transducers for imaging, monitoring and therapy.

Imasonic collaborates with research labs, start up and SME companies and large organisations; Imasonic supplies them from research prototypes to serial quantities of transducers.

Partners: Companies and research labs willing to collaborate within R/D partnership notably for the purpose of developing innovative medical devices dedicated to ultrasonic imaging, monitoring and/or therapy.

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HEALTH / PHYSIOLOGY



Innovation in motion

KiwiCube is specialised in design and development of solutions dedicated to **physical and cognitive training** and rehabilitation. KiwiCube offers **e-health** smart systems that perfectly fit preventive as well as curative courses.

KiwiCube service example:

A manufacturer wants to develop a solution aimed at helping elderly people to remain independent in medical institutions. KiwiCube will support his clients in product's **design** and **development** phases:

- **specific needs** identification of elderly people (interface design, practical device **usability**...)
- test, analysis and adapted physical **exercise validation**
- development of an **interactive platform** that enables independent physical activity
- algorithm platform integration in order to design a **training programme** adapted to each user
- **activity** device design that saves the physical activity;
- activity **analysis** and progress **report**

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HEALTH / MEDICAL
DEVICE



MICRO-MEGA® gathers all the manufacturing process: from design to delivery

Since more than a century, MICRO-MEGA® company designs, manufactures and sales dental surgical instruments in the heart of Besançon, the French watchmaking and microtechnology capital. It's here that the worldwide recognised specialists in endodontic products (treatment of the dental pulp and conservative dental care) produce high-quality instruments for dental professionals all over the world.

All the manufacturing steps – from design to delivery – are gathered under one roof: which provides MICRO-MEGA® with a perfect process of product control as well as an optimised traceability and follow-up.

MICRO-MEGA®'s know-how include:

- **design:** products design according to partner dental surgeons specifications
- **bar turning:** files trimming with an optimal accuracy at the micron scale
- **electro polishing:** surface condition improvement
- **thermal treatment:** mechanical property modifications
- **assembly and packaging:** product semi-automated line finishing in controlled atmosphere areas
- **laboratory:** product testing according to regulatory benchmarks or specifically developed approaches

Its technical skills, unique know-how, its ability to be always more innovative and its quality policy enable MICRO-MEGA® to provide innovative and high-tech products. Its latest breakthrough product in terms of endodontic treatment named 2 Shape – heat-treated file delivered in a sterile blister pack– is a perfect example.



Certifications:
ISO 9001: 2008
NF EN ISO 13485: 2012



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HEALTH / MEDICAL
DEVICE



 MIRAVAS

Vbox: The solution for the treatment of the whole venous pathology

The venous pathology affects nearly 20 million French people, of which half have varicose veins, and then represent a huge human and economic challenge for public health.

Built on the model of its European neighbours, the French Health Insurance fosters the adoption of new minimally invasive techniques and development of outpatient surgery in order to combine patient welfare and health expenditures control.

Miravas innovative answer is to offer devices at competitive prices and medical act friendly, enabling to treat the whole venous pathology in outpatient departments.

- **Vbox**

Treatment by water vapour.

- **Vbox hybrid**

Treatment combining water vapour and radiofrequency.

Today, Miravas strengthens its presence on varicose veins treatment market and is seeking to extend its use to other therapeutic indications.



Certifications:
NF EN ISO 13485: 2012



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HEALTH / MEDICAL
DEVICE



Real time fall detector device, without carried sensor



Certifications:

CEM (in progress)
Marquage CE (in progress)



The Morphée+ device is a unique fall monitoring system that:

- protects people **private life** thanks to image capture absence
- resolves the problem of carried sensor oblivion or rejection: Morphée+ operates **without any carried sensor**

The Morphée+ device is designed to alert in minutes caregivers of **falls** and worrying health parameters.

It thus enables to maintain people home-based longer and **safe**. It also can be set to alert negative effects of some treatments.

Morphée+ system reduces care costs as it **anticipates** the occurrence and worsening of diseases, reduces accommodation costs as it **automates** a part of registration statements which are currently done manually by caregivers. It finally reduces medical and financial consequences of fall, quickly alerting caregivers.

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HEALTH / MEDICAL
DEVICE

oneFIT
an EOS imaging company

From medical imaging to the operating room: a customised approach for the prosthesis fitting process, that combines surgical planning software and 3D printing



Certifications:
EN NF ISO 13485: 2012

oneFIT medical develops and markets patients' **customised solutions** for **orthopaedic surgery**.

From anatomical model –achieved following 3D reconstruction of DICOM images coming from scanners and MRI or directly from 2D/3D EOS images- we design innovative medical devices that perfectly fit the patient's bone structure and allow us to reproduce **preoperative planning** parameters.

oneFIT medical is a subsidiary firm of the EOS imaging group, that designs, develops and markets EOS®, a breakthrough and patented low dose medical imaging system, based on the discoveries of Nobel Prize winner in Physics Georges Charpak.

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HEALTH / MEDICAL
DEVICE



PLASTIFORM

SOLUTIONS THERMOFORMÉES

Thermoforming innovation for biomedical industry



Certifications:
NF EN ISO 9001: 2015



PLASTIFORM was created in 1968 and has been working in the medical sector for more than 40 years. With its strong knowledge in raw materials mechanical and physical properties, the company caters for the toughest packaging needs, or for **thermoforming** requests and achievement of high efficiency technical components according to clients' specifications.

For **packaging**:

- **isothermal** conditioning system for drugs and organs
- customised and ancillary conditioning **trays**
- container collecting **analysis wastes**
- specific and customised **blister packs**: small volumes

Technical components:

- disposable consumable item for **analysis**, achieved with high efficiency and thin materials; large volumes
- **electrical insulation** for electronic medical devices.
- great thicknesses **overturning** for medical devices as analysis machines, cryogenics...

High efficiency specific materials: PEEK, PEI, PPSU, special polycarbonate, PETG, KYDEX...

Areas of expertise: surgery, dental, pharmacy, screening laboratories, veterinary.

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HEALTH / MEDICAL
DEVICE



Electronics
Optoelectronics
Mechatronics



Certifications:

Research Tax Credit accredited
Research Department
Certified manufacturing facility
UL / ISO 9001 / ISO 13485



FCE - POLYCAPTIL: technological multi-skills

POLYCAPTIL has been developing and manufacturing electronically based products for 25 years (study, patterns, routing, modelling, and prototyping of electronic boards) as well as mechanical solutions related to electronics.

The world is now digital and connected and Polycaptil is specialised in software development and also offers complete Hardware, Firmware, Software electronic solutions

FCE is a Polycaptil subsidiary company that manufactures, programs and tests customised technical electronic boards.

With a technology investment for an optimal service and a mastered quality (40000 SMD line components per hour / Selective series / 3D Automatic Optical Inspection (AOI 3D) / In situ Functional testing / Robotised coating) 70 % of electronic boards manufactured by FCE are intended for medical and laboratory instrumentation.

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HEALTH /
BIOTECHNOLOGIES

 **ProviSkin**
Innovation For Skin Research

Support in the implementation of innovative devices and studies in the cutaneous sector



Certifications:

ProviSkin is GLP and Research Tax
Credits certified

ProviSkin is a company that works on innovative devices in the cutaneous field. Its main goal is to offer its clients high added value systems thanks to the design of patented equipment designed for ex-vivo/in-vitro studies (dermal absorption, wettability, mechanical properties...).

Thanks to its team composed of engineers and scientists, ProviSkin also supports its clients providing them with devices specifically designed according to their issues/specifications.

In order to enable its clients to achieve their researches, ProviSkin offers the following solutions:

- sale of skin tissues from all origins (human, animal)
- sale of patented devices for studies in the skin sector (Franz cells, electric resistance studies...)
- scientific and technical support of the client for the implementation and/or design of a product in the cutaneous sector



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HEALTH / MEDICAL
DEVICE



STATICE, key reference subcontractor for Medical Devices design and manufacturing

STATICE, key reference subcontractor for Medical Devices design and manufacturing.

STATICE is a microtechnology and biomaterials service provider that achieves customised and innovative devices and supports for its clients from study to production. STATICE is a **reference for development and production of implants, catheters, instruments and laboratories equipment.**

Medical devices designed by STATICE are used in all activity sector that are cutting-edge technologies demanding (cardiovascular, neurology, urology...).

With a research unit composed of 30 people (doctors, engineers, technicians) and a mechanical and electronic workshop, STATICE carries out over a hundred industrial projects every year. STATICE is known in Europe for its innovative capacity.

Project industrialisation is managed by a 4 people team that ensures implied process robustness IQ / OQ / PQ, R&D tests) and DMR file writing.

The production team is made of 70 people who work within a controlled environment (ISO5 and ISO7). Production is driven by an ERP.



Certifications:
ISO 13485: 2016
ISO 9001: 2015

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JOIN INNOV'HEALTH AND BENEFIT FROM ITS NUMEROUS ADVANTAGES

OPEN TO ALL
(members and non-members)

VISIBILITY & NETWORKING

- French Tech (Health Tech)
- Promotion of members' expertise
- Thematic workshops
- Business clubs
- International network

EXPERTISE & PROFICIENCY

- Skills accelerator
- Market study and regulatory watch
- Expert groups
- Trainings
- Regulations and standards

BUSINESS

- Event organisation (business conventions, B2B meetings...)
- Innovative project labelling
- Business creation
- Mutualisation of individual demands



innov'Health

Health Industry Competitiveness Cluster

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