# **GROUPE**

## HEALTHCARE PRODUCT SAFETY EXPERT



LEADER IN REGULATORY SAFETY FOR MEDICAL DEVICES IN FRANCE

#### YOUR PROJECTS AT THE HEART OF OUR MISSION!

#### Healthcare products follow a life cycle which we fully control to guide you at every step and in all your undertakings.



- Choice of manufacturing processes
- Marketing authorization
- Production and distribution
- Monitoring, analysis and control

From the concept to monitoring of your production, our teams of experts guide you and offer you appropriate solutions.

#### Our collaboration will enable you to:

- or Ensure compliance with standards & regulations
- W Maintain better control over subcontracting
- V Control all project development phases
- or Optimize the tests to be deployed for optimum control at the best price

For more than 25 years, the lcare Group has been placing its expertise at your disposal for meaningful cooperation.

## cofra Accréditation n°1-6921 Portée disponible sur www.cofrac.fr



Accréditation n°1-1021 Portée disponible su LULIU COECAC EL

MEMBER OF STANDARDISATION COMMITTEES

#### **IS0**

- 𝐨 Gamma radiation sterilization
- & Biological indicators clinical evaluation of Societation control for
  - cleanrooms
  - or Dentistry
    - & Dental implants
    - & Biological and clinical evaluation of medical devices
- ✓ Cvtotoxicity
- requirements
- Systematic approach to biological evaluation and terminology

Teffects on blood 𝐨 Implantation

#### CERTIFICATION AND RECOGNITION





W Biological and medical devices

AFNOR

𝐨Oral medicine

OUR TEAMS GUIDE YOU AND SHARE THEIR EXPERTISE IN ALL STEPS OF THE HEALTHCARE PRODUCT LIFE CYCLE.



#### **VALIDATION & QUALIFICATION**

- **v** Process validation
- ${\mathbb V}$  Qualification of software



#### **METHODS & DEVELOPMENT**

- **v** Customized tests
- **V** Optimization
- Custom manufacturing (biological indicators, etc.)



#### LABORATORY TESTS

- **The Microbiological analyses**
- V Physical and chemical tests
- The of th



#### BIOTOX

- **w** Biocompatibility
- **𝔍** Toxicology
- 𝐨 Mutagenicity /genotoxicity
- 𝐨 Safety pharmacology
- V Aquatic ecotoxicity/biodegradability



#### SERVICE OFFER Technical assistance

- e rechnical assistant
- 𝐨 Audit
- V Monitoring and regulatory watch
- **V** Consulting

Icare, approved training organization - approval number: 83 63 02860 63

Scan the QR code to get all of our staff member's contact details



#### ICARE IS AN APPROVED TRAINING CENTER

Approval number : 83 63 02860 63 Formation@groupeicare.com

WANT TO JOIN OUR TEAM?

recrutement@groupeicare.com

#### **KEY FIGURES**

#### **ICARE BIOPÔLE**

LABORATORY TESTS METHODS & DEVELOPMENT VALIDATION & QUALIFICATION SERVICE OFFER

Biopôle Clermont-Limagne 63360 St-Beauzire - France

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#### **ICARE BIOTOX**

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#### **ICARE SWITZERLAND** Eplatures - Grise 17

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#### **ICARE DO BRASIL**

Rua Octavio Teixeira Mende Sobrinho, 35 Vila Santa Catarina - Sao Paulo - Brasil



4 sites on 2 continents & a global reach



8.500 sq. m including 3.600 sg. m of cleanrooms



+ 220 employees & 35 professions



+ 200 standard services

### www.groupeicare.com

