



Your tests
in complete confidence

MedicalGroup laboratory

Our expertise to support your compliance



Our microbiology and physico-chemistry units will put their expertise and technical skills at your disposal to offer you the solution best suited to your needs.

Whether it is for routine testing, or to support you in your product development and marketing projects, our teams are on hand to advise you and help you find the best solution.



The laboratory is accredited to ISO 17025, with Cofrac testing accreditation no. 1-6644, scope available on www.cofrac.fr

Contamination control

Our expertise in a range of biological and microbiological techniques means we can meet your needs for the following tests :

The tests	Reference standards
Bacterial endotoxins (LAL)	Ph. Eur. 2.6.14, USP <85> and <161> Method D, ISO 11737-3
Initial bioburden (IBB)	ISO 11737-1
Sterility tests	ISO 11737-2, Ph. Eur 2.6.1 et USP <71>
Initial and routine dose audits	ISO 11137-2
Identification of microorganisms by Maldi TOF, PCR sequencing and Gram staining	

We also draw up test method validation protocols and reports for bioburden, bacterial endotoxin and sterility tests.

Adherence to deadlines and possibility of emergency packages

Packaging performance and stability

The knowledge of the requirements related to :

- the product packaging solutions
- the performance they must achieve in terms of sterile barrier, resistance to transport and storage conditions,

enables us to help you define sampling plans, validation protocols and associated tests.

Cleaning validation



A new range of implants to clean ?
A new machining process ?
New materials in contact ?

The ISO 19227 standard defines the criteria and tests to be carried out to validate cleaning.

Our laboratory can advise and guide you.



The tests	Reference standards
Tensile strength	EN 868-5 and ASTM F88/F88M
Visual inspection	ASTM F1886
Manual peelability	EN 868-5
Seal leak detection	ASTM F1929 and ASTM F3039
Accelerated aging	ASTM F1980
Transit simulation	ASTM D4169 and ISTA
Microbial barrier	ASTM F1608
Bubble test	ASTM F2096

The tests	Reference standards
Organic contaminants (TOC and THC)	EN 1484 and ISO 9377-2
Inorganic contaminants	ISO 10993-12
Cytotoxicity	ISO 10993-5
Bioburden	ISO 11737-1
Bacterial endotoxins (LAL)	Ph. Eur. 2.6.14, USP <85> et <161> Method D, ISO 11737-3
In addition, depending on the product material : corrosion test	ASTM A967 (Methods A and E)

Proximity : constant availability and interaction with our teams

Coating characterisation

We carry out a complete assessment of the performance and properties of powders and coatings, in accordance with the requirements of ISO 13779, ISO 13179-1, ASTM standards and FDA guidances.

To be compliant, powders and coatings must pass 3 families of tests :

The tests

Chemical tests

Phases, crystallinity and Ca:P ratio by XRD	ISO 13779-3
Heavy metals and trace elements on HA	ISO 13779-3
Titanium chemical analysis	ISO 13179-1 and ASTM F1580
Corrosion	ASTM A967 (Methods A and E)
Solubility and dissolution	Guidance FDA, ISO 13779-6, ASTM F1926/1926M
Infrared spectroscopy	Guidance FDA

Mechanical tests

Tensile strength	ASTM F1147 and ISO 13779-4
Static shear strength	ASTM F1044
Fatigue shear strength	ASTM F1160
Abrasion Taber	ASTM F1978
Fatigue bending	ASTM F1160

Morphology tests

Thickness and porosity	ASTM F1854
Roughness (Ra, Rt)	NF S94-071
Scanning electron microscope	

Proactivity and expertise

Personalised support for your projects

You have a development project,
and need a partner to carry it out ?

We can provide you with technical advisers to help
manage your project and perform tests.



Tracking and monitoring changes in standards



Thanks to our regulatory monitoring, we are
able to identify changes in standards.
At any time, our team can help you analyse the
impact of these changes and the need to update
or adapt your practices.



Contact us now !

Do not hesitate to contact us for other types of tests related to your products or projects.
We will study your request in-house, or in conjunction with partner laboratories.

Our laboratory is located in Saint-Priest, in the Lyon metropolitan area, on a new, high-capacity site.
It has a modern working environment and equipment, and draws on expertise developed over more than 30 years.

