



# MEDICAL DEVICES & HEALTHCARE

Your Testing Center and  
Certification Partner



# ONE STOP SHOP SOLUTION

Our medical device testing specialists evaluate the durability, safety, cybersecurity, and aging performance in **Types and Classes of medical products**.

We bring deep technical, clinical, and regulatory expertise across a wide range of medical technologies, supported by a global network of laboratories, services, and experts.



## TESTING SERVICES

- Mechanical
- Chemical
- Safety
- Cybersecurity



## CERTIFICATION SERVICES

- **ISO 13485** Quality Management System
- **2017/745 MDR** Product Conformity Assessment



## MARKET ACCESS

- **MDR/CE** Marking
- **FDA**
- **NMPA** CMA accredited Labs



## CERTIFICATION SERVICES FOR MARKET ACCESS

### MEDICAL DEVICE REGULATION (EU) 2017/745 (MDR) | Notified Body

As a Notified Body for EU MDR, we certify active and non-active devices. We have two Notified Bodies that collaborate closely with our laboratory network around the world. Our goal is to enhance patient safety through a comprehensive life-cycle approach.

#### Benefits:

- Stronger patient safety
- Rigorous clinical evidence
- Improved traceability (UDI system)

### QUALITY MANAGEMENT SYSTEM ISO 13485 Certification

As an **ISO/IEC 17021** accredited certification body, we provide certification services for the Quality Management System in the Medical Industry (ISO 13485).

#### Benefits:

- International compliance
- Lifecycle control
- Market access
- Efficiency
- Trust and credibility

# TESTING SERVICES

## BIOMECHANICAL TESTING

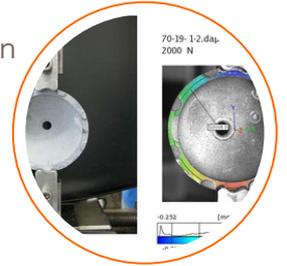
Full accredited labs

- Wear and Fatigue
- Corrosion
- Mechanical and Physical Tests on PE
- Metallography – Microstructure
- Materials and Coatings
- Sample Preparation
- PE Particle Analysis



## VIRTUAL TESTING & SIMULATION

- Optical 3D measurement technology
- Anodising, cleaning, packaging
- Simulation & calculation:
  - ◆ Orthogonal experimental design
  - ◆ Finite-Element-Analysis
  - ◆ Biomechanical simulation
  - ◆ Virtual aging tests
  - ◆ Long-term behavior



## CHEMICAL TESTING

ISO 10993 | ISO 19227 | ASTM 1980

- Biocompatibility Testing
- Cleaning Validation
- Stability Testing
- Characterization of Biomaterials and Medical Devices
- Cleanroom Characterization



## PACKAGING TESTING

ISO 11607-1 | ASTM D4169 | ISTA

- Primary Packaging Validation
- Real-time and Accelerated Aging
- Temperature Validation
- Transit Test Simulation
- Sterile Barrier
- Stability Validation



## SAFETY & ESSENTIAL PERFORMANCE

AAMI/IEC 60601 | 61010

- EMC & Radio Testing
- Electrical Safety
- Functional Safety
- Environmental Testing
- Acoustics Testing
- Photobiological Testing



## CYBERSECURITY ASSESSMENT

- Protection of patients, data, and healthcare systems from cyberattacks
- Regulatory compliance and Cyber Resilience
- International standards and guidelines:
  - ◆ EU MDR/ MDCG 2019-16 EU
  - ◆ FDA Guidance
  - ◆ NMPA
  - ◆ IEC TR 60601-4-5
  - ◆ IEC 81001-5-1
  - ◆ IEEE 2621



## ABOUT US

We're Applus+ Laboratories, a division of the Applus+ group that provides testing and certification to improve the competitiveness of our client products and encourage innovation.

Headquartered in Barcelona, Spain, our growing network of multidisciplinary laboratories worldwide plays a key role in advancing the critical industries, with a strong focus on medical devices. Our laboratories hold accreditations from DAkKS, ENAC, COFRAC, and CMA, guaranteeing compliance with international standards and local regulations.

Experience the Applus+ Laboratories advantage—where excellence meets reliability, efficiency, and safety, propelling your business towards unparalleled success.

Our facilities, expertise, and capabilities allow us to partner with renowned technological corporations worldwide, and we can't wait to partner up with you next to help you meet your market needs.

## ACCREDITATIONS

- ISO/IEC 17025** - Accreditation Certificate in France, Germany, Spain, USA, Canada and China
- ISO/IEC 17021-1**
- ISO/IEC 17065**

## NOTIFICATIONS

- MDR Notified Body  
**NB 2764**  
**NB 3121**

## CERTIFICATION

- CE Marking**
- NRTL**
- CB Scheme** (CBTL & NCB)
- QMS ISO 13485**

## GLOBAL NETWORK OF LABORATORIES FOR MEDICAL DEVICES



### CANADA

- Toronto
- Ottawa

### USA

- Baltimore, MD
- Durham, NC
- New Castle, PA
- Ithaca, NY
- Houston, TX

### FRANCE

- Bordeaux

### GERMANY

- Dresden
- Bremen

### CHINA

- Shanghai
- Jiangsu
- Shenzhen

### SPAIN

- Barcelona
- Granada

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## CONTACT US

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