



TESTING FOR BIOMEDICAL AND ELECTROMEDICAL



WE MAKE YOU FEEL SURE

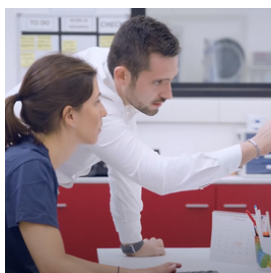
TEC Eurolab is a competent, independent and impartial third-party industrial laboratory, accredited UNI CEI EN ISO/IEC 17025:2018, 17024:2012 and 17065:2012 standards, which guarantee its competence, independence and impartiality. NADCAP accreditation and UNI EN 9100:2018 certification also attest to its expertise in the aerospace and defence industry.

Since 1990, with over thirty years of experience, we have become a multidisciplinary centre of excellence for materials analysis, non-destructive testing, training and certification. We assist manufacturing companies in gaining and verifying the maximum performance of products and processes, with safety and quality.

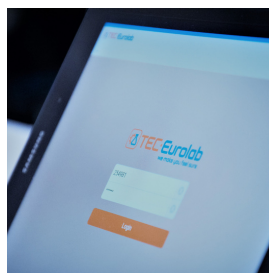
We are here to help you find the best solution to your needs.



TESTING



TRAINING



CERTIFICATION

TESTING FOR BIOMEDICAL AND ELECTROMEDICAL



YOUR CHALLENGE

Designing and developing safe medical devices, guaranteeing compliance with European and International Regulations, optimizing production processes to meet growing needs, designing more performing and easy-to-use products for both patients and healthcare personnel: these are just some of the main challenges that companies in the biomedical sector have to face every day.

It is therefore necessary to be supported by a technologically reliable partner who helps companies reduce time to market and supports them in the study of performance, validation of new devices and the use of new materials.

QUALITY ACCREDITATIONS

EN 9100:2018 - UNI EN ISO 9001:2015 (SAI GLOBAL)

UNI CEI EN ISO/IEC 17025:2018 - testing laboratory (ACCREDIA)

MIUR recognition (Ministry of Education, University and Research) - approved Laboratory No. 222 of the Suppliers' Register for Emilia Romagna

ART-ER – Territory Research Activities Accreditation

MAIN REFERENCE STANDARDS

ISO 16371-2: Industrial computed radiography with storage phosphor imaging plates

ISO 3452-1: NDT general principles with penetrating liquids

ISO 15708-3 : Radiation methods for computed tomography

ISO 9712: Qualified personnel, level II and III for MT, PT, UT, RT, CT, VT testings

OUR SOLUTION

For the transversality of the services offered and for the accreditations held, TEC Eurolab is the ideal partner to support companies operating in the biomedical sector: from raw material producers, to plastics processing companies, metal alloys processing using traditional or additive technology, up to the manufacturers of electro-medical devices. The activities of TEC Eurolab are inserted in support of all the production phases: from the concept, which is born in the R&D departments, to the industrialization phase and subsequent production, structuring together with the customer a test plan adequate to the needs of validation of the medical device or material used in compliance with the main European regulations and regulations in force. Relying on an independent test laboratory allows you to identify and prevent defects and errors from the early stages of product design and development, maximize product safety and reliability, limiting costs related to non-quality.

BIOMEDICAL SERVICES IN TEC EUROLAB



WHAT IS YOUR PRODUCT?

TEC Eurolab can support you in carrying out destructive, non-destructive and functional tests depending on the type of your product and the biomedical sector in which your company operates.

PROSTHESES

- NON-DESTRUCTIVE ANALYSIS (NDT TEST)
- METALLURGICAL AND FAILURE ANALYSIS
- FUNCTIONAL TESTS AND PRODUCT VALIDATION
- CHEMICAL AND PHYSICAL ANALYSIS ON METALLIC MATERIALS
- ANALYSIS AND SUPPORT FOR THE ADDITIVE MANUFACTURING PROCESS
- STATIC AND DYNAMIC MECHANICAL TESTS
- REVERSE ENGINEERING

ELECTROMEDICAL

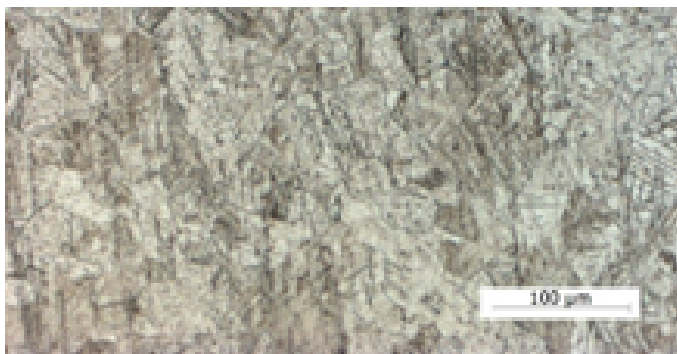
- ENVIRONMENTAL AND THERMAL SHOCK TESTS
- ROHS ANALYSIS AND CERTIFICATION
- FUNCTIONAL TESTS AND PRODUCT VALIDATION
- QUALITY CONTROL OF THE SUPPLY CHAIN

DISPOSABLE DEVICES

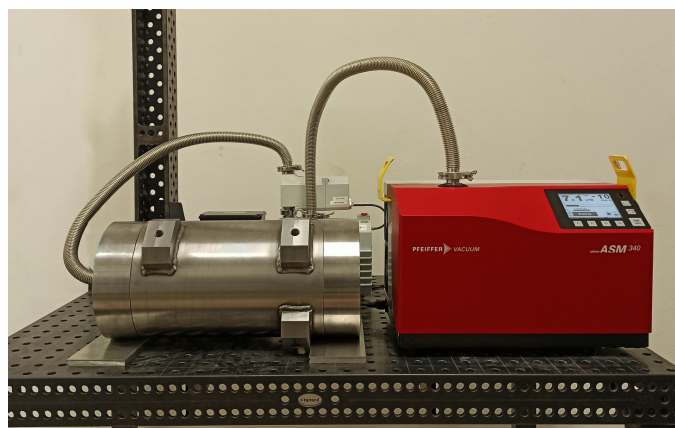
- DIMENSIONAL CHECKS
- SPC ANALYSIS (STATISTICAL PROCESS CONTROL)
- FUNCTIONAL TESTS AND PRODUCT VALIDATION
- CHEMICAL AND PHYSICAL ANALYSIS OF PLASTIC AND METAL MATERIALS
- VALIDATION OF BONDING AND WELDING
- ENVIRONMENTAL TESTING AND ACCELERATED AGING
- REVERSE ENGINEERING

MEDICAL-SURGICAL DEVICES

- FUNCTIONAL TESTS AND PRODUCT VALIDATION
- CHEMICAL AND PHYSICAL ANALYSIS ON PLASTIC AND METAL MATERIALS
- ANALYSIS OF CAUSES OF CORROSION
- ENVIRONMENTAL TESTS
- DIMENSIONAL CHECKS



Co - Cr alloy microstructure molded by EBM additive technology



NON-DESTRUCTIVE TESTS

Industrial Tomography: 6 MEV LINAC; 450 kV minifocus; 240 kV microfocus

Radiographic Inspection: 160 kV e 320 kV Radiographic inspection on film and digital (RT, CR, DR)

Superficial Methods: Penetrant liquids (PT)

ENVIRONMENTAL AND ACCELERATED AGING TESTS

Corrosion resistance tests (ASTM B117, ISO 9227)

Aging and thermal cycles in a climatic chamber (temperature and humidity variation)

Artificial light accelerated aging tests (Xenon test UNI EN ISO 4892-2 and UV condenser UNI EN ISO 4892-3)

Thermal shocks

FAILURE ANALYSIS METAL AND POLIMERIC MATERIALS

Main causes of breakage and damage investigation:

Corrosion

Design errors

Anomalies during the production process

Fatigue

Damage caused by unsuitable environmental exposure (temperature, humidity, aging due to exposure to sunlight...)

Fragile Breakages

SCC

Ductile overload

METALLURGICAL ANALYSIS

Scanning electron microscope (SEM) observations and EDS microanalysis

Macrographic and Micrographic analysis

Hardness: Brinell, Vickers, Rockwell

Evaluation of the effects from heat treatments or HIP

CHEMICAL AND PHYSICAL ANALYSIS METALLIC MATERIALS AND POWDERS

Chemical analysis of metal alloys ICP-OES, XRF, SPARK-OES + determination of C-S-H-O-N - ED-XRF (PMI)

Measurement of thermal conductivity by LFA and of the coefficient of linear thermal expansion (CTE) with dilatometer

SEM electron microscope observations + EDS microanalysis

Analysis of metal powders characteristics for Additive Manufacturing: Chemical analysis (ICP-OES, XRF); Flow rate (ASTM B213); Moisture content; Particle size distribution ASTM B822; Laser technique + SIEVES (ASTM B214); Density according to ASTM B962

CHEMICAL AND PHYSICAL ANALYSIS POLIMERIC MATERIALS

Chemical analysis by FT_IR infrared spectrophotometry

Thermal Analysis: Differential Scanning Calorimetry (DSC) and Thermogravimetric Analysis (TGA)

Measurement of thermal conductivity (LFA method) and of the linear thermal expansion coefficient

Liquid chromatography (HPLC / UPLC)

Shore A - D hardness

Flow rate measurement (MFI - ISO 1133)

Compatibility of plastics with fluids

STATIC AND DYNAMIC MECHANICAL TESTS METALLIC ALLOYS AND AM PRINTING

Tensile tests at room temperature up to 600kN (ASTM E8, UNI EN ISO 6892-1)

Hot tensile tests up to 1200 ° C and 100kN (ASTM E21, UNI EN ISO 6892-2)

HCF fatigue tests up to 1100 ° C (ASTM E466) and LCF fatigue tests (ASTM E606)

Lap shear tests (ASTM D5868, ASTM D1002, ASTM D5656)

Fracture mechanics tests (FATIGUE CRACK GROWTH - ASTM E647)

PRODUCT VALIDATION CUSTOM FUNCTIONAL TESTS

Study, design and implementation of specific test systems to simulate the real operating conditions and use of the component in order to assess its reliability and verify its performance. Main instruments used and services offered:

Pressure test benches: burst test, leak test, pulsating pressure test (Up to 35bar in air, 600 bar in oil and at different temperatures, from -70 ° C to + 180 ° C)

Custom test rings for both static and dynamic functional tests with pneumatic actuators equipped with different load cells (Force applicable from a few Newtons up to 18 kN) and multi-channel controller up to 4 axes simultaneously.

Electromechanical systems for both static and dynamic functional tests, high speed tractions and compressions. Tests can be carried out in a climatic chamber from -40 ° C to + 180 ° C

Drop tower for impact resistance tests (on components and connectors)

Use of Strain Gages for monitoring local stresses and deformations

STATIC AND DYNAMIC MECHANICAL TESTS POLIMERIC MATERIALS

Dynamic Mechanical Analysis (DMA)

Tensile tests up to 250 ° C (ASTM D638, ISO 527)

Bending tests up to 250 ° C (ASTM D790, ISO 178)

Compression tests (ASTM D695, ISO 3386)

Peel tests 90 ° / 180 ° ASTM D3330, ASTM D1876)

Fatigue behavior characterization of plastic materials (from -40 ° C to + 180 ° C)

PRODUCT VALIDATION DIMENSIONAL CHECKS AND STATISTICAL PROCESS ANALYSIS (SPC)

Zeiss three-dimensional coordinate machine (CMM)

Programmable optical VMM OGP

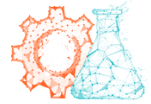
3D GOM optical machine with structured light in a robotic island

Anthropomorphic arms with touch probe and laser head (dimensional checks, reverse engineering and cad comparison)

Roughness and Profilometer

Minitab Statistical Software

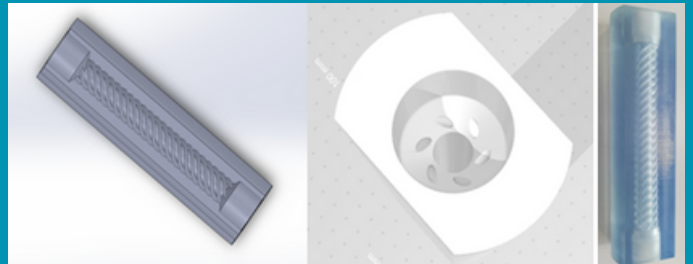
SOME ACTIVITIES CARRIED OUT IN THE LABORATORIES FOR BIOMEDICAL



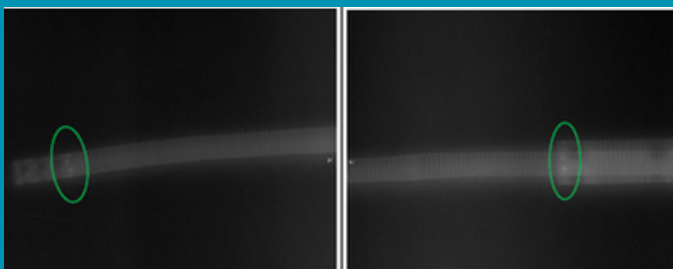
NON-DESTRUCTIVE TESTING



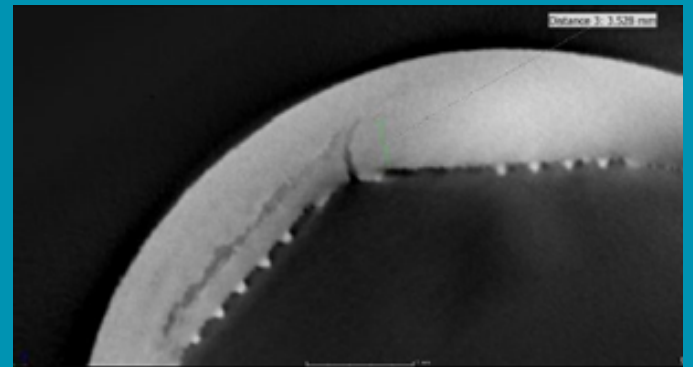
Identification of linear or non-linear indications on the surface - PT analysis



Obtaining CAD models of finished components - reverse engineering by tomographic analysis



Radio verification - ASTM F640-12 radiopaque detectability marker



Analysis of internal defects (porosity, failed fusions, vacuum, air bubbles ...) carried out using industrial tomography

PRODUCT VALIDATION CENTER

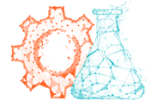
Packaging

- Peeling test UNI EN 868-5 Annex E
- Sealing strength test UNI EN 868-5 Annex D/ ASTM F88
- Dye penetration Test ASTM F1929
- Pinholes test on plastic film UNI EN 868-5 Annex C
- Bubble test (ASTM F 2096)
- Burst Strength test (ASTM F 2054M)

Prosthesis and implantable medical surgical devices

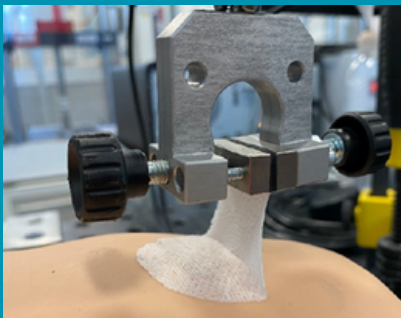
- Static and Fatigue Tests on Implantable Spinal Devices (ASTM F1717, ASTM F2706, ASTM F2077)
- Fatigue tests on hip implant prosthesis (ISO 7206, ASTM F2068)
- Fatigue tests on tibial prosthesis (ASTM F 1800, ISO 14879) Test on bone screws (ASTM F543, ISO 6475)
- Fatigue test on dental implants (ISO 14802)
- Static and dynamic resistance to bending and stiffness of bone plates (ASTM F382, ISO 9585)
- Static and dynamic resistance of extra-discal spinal structures (ASTM F2624)
- Fatigue Test on External Fixators (ASTM F1541)

SOME ACTIVITIES CARRIED OUT IN THE LABORATORIES FOR BIOMEDICAL

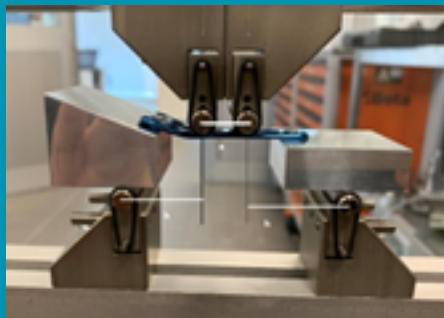


Disposable plastic or metallic devices

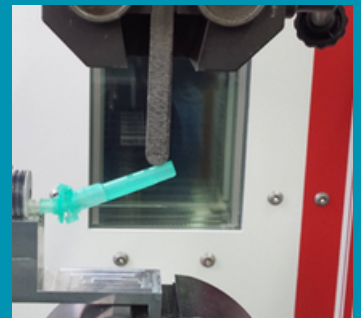
- Needle and Syringe Test (ISO 11040-4 / 8)
- Determination of the actuating force of the plunger for disposable syringes (EN ISO7886-1)
- Traction test on intravascular catheters (ISO 10555)
- Measurement of the withdrawal and insertion force of infusion sets (ISO 8536-4)
- Cut Injury Protection - Sharp Object Protective Features for Disposable Hypodermic Needles, Catheter Introducers and Blood Collection Needles (ISO 23908)
- Pressure tests on components for welding / assembly validation
- Dimensional analysis and functional tests on luer connections (ISO 80369)



Peel test



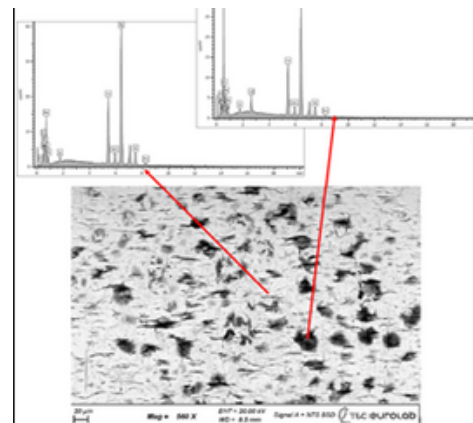
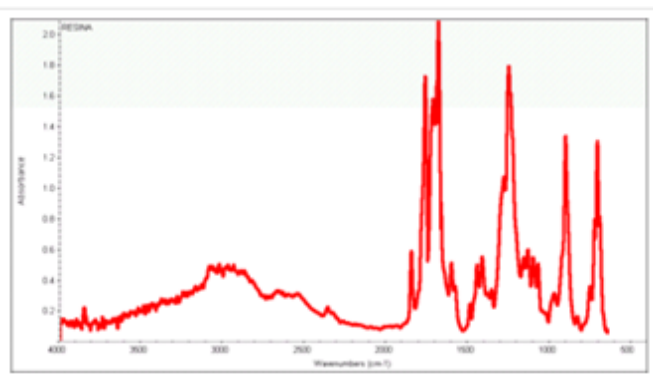
Fatigue tests on ASTM bone plate F382



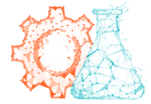
ISO 23908: 2011 - Performance measurement of protection against sharp devices

CHEMICAL AND ENVIRONMENTAL LABORATORIES

- Leaching test on Metals in accordance with the guide of the European Council "CM / Res (2013) 9 EDQM"
- Global and specific migration from plastics in accordance with the European regulation EU Reg. 10/2011
- Stainless steel leaching test in accordance with D.M 21/03/1973 and related updates
- RUBBER release test in accordance with DM 21/03/1073 RoHS III compliance check (DIRECTIVES 2011/65 / UE + 2015/863 / UE)
- Stability tests and accelerated aging studies on packaging and medical devices (ASTM F1980 / ISO 11607)
- Chemical characterization of metallic and plastic materials according to ISO 10993-18
- Corrosion analysis of needles and surgical instruments



SOME ACTIVITIES CARRIED OUT IN THE LABORATORIES FOR BIOMEDICAL



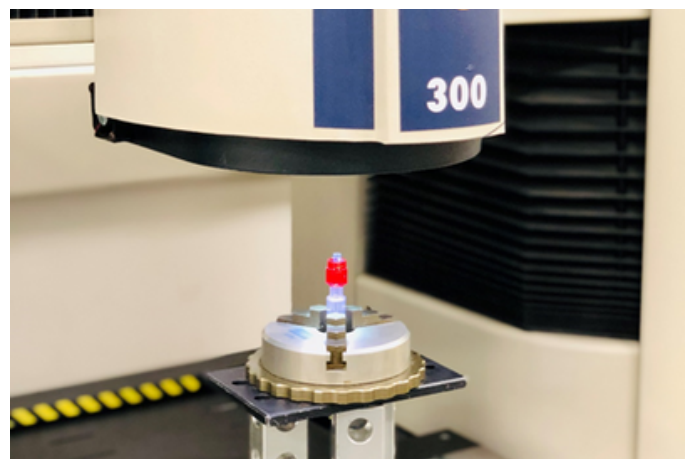
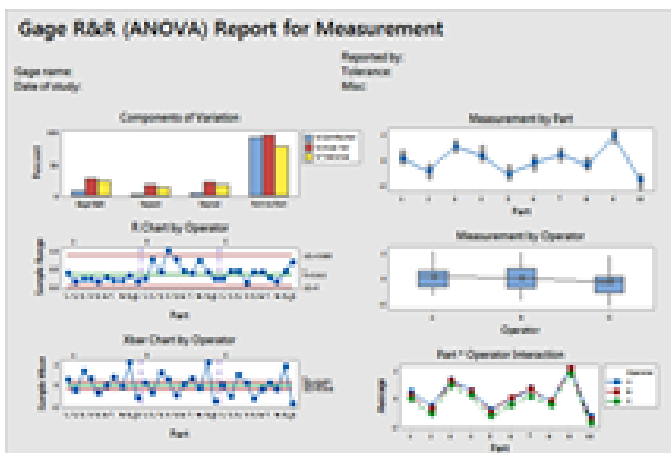
DIMENSIONAL CONTROL DEPARTMENT

Disposable plastic or metallic devices

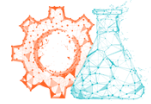
- Gage R&R studies and drafting of control procedures for validation of measurement methods
- Quality control and process capability studies
- Dimensional survey of complex dimensions to be controlled or related to internal geometries, acquiring the volume of the object by means of an industrial tomograph and subsequently validating the control method by comparison with CMM and optical machine measurements
- Technical support on customer's site for the development of measurement programs on optical machines and training on their use
- Quality control of incoming supplies

Prosthesis and implantable medical surgical devices

- Reverse Engineering
- Critical dimensions control



TRAINING FOR THE BIOMEDICAL SECTOR



ACADEMY

TEC Eurolab Academy designs growth paths with the aim of helping companies and professionals to acquire the skills necessary for their career development and for those who will be the pivotal roles of the future: metrologists, inspectors, welding experts, test representatives, additive designers.

The courses can be delivered in mixed mode, both in classrooms and online and with the possibility of carrying out practical tests in the laboratories.

Thanks to learning tests it is possible to verify the effectiveness of the course and guarantee precise feedback to the client. The proposal includes courses in inter-company and single-company mode, scheduled or on request. This flexibility allows companies to optimize the economic and temporal resources, guaranteeing a quality and personalized service.

The thirty-year experience of TEC Eurolab in the testing field, in addition to the partnerships and external collaborations with some of the most important international bodies (TWI, CERN, ASM ...) means that TEC Eurolab Academy can support companies and their professionals in the acquisition of the necessary skills on the most advanced technological frontiers.

TRAINING COURSES

Development of biomedical products

The course intends to transfer to students the basic notions of the regulations governing quality and risk management in the field of medical devices, CE and FDA standards. The aim is to provide the knowledge and tools useful for the correct design of products and related technical files. *Tecnologia dei materiali biomedicali*

Biomedical materials technology

The course examines the classification and characterization of the various types of biomedical materials: metallic, polymeric, ceramic and composite. The sterilization and biodegradation of materials are also addressed, with practical examples of industrial applications and manufacturing processes. The focus will be on Additive Manufacturing technology applied to the world of biomedical materials. The course will deal with the topics both from a theoretical point of view and by exploring practical cases.

WE MAKE
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SURE



OUR SITES

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