



## Medical Devices Division



is a TIC company which, by controlling numerous laboratories nationwide, has created a new leading group in Italy for testing, research, consultancy and certification services.



### Our laboratories • Biochem

Biochem has been operating in the biomedical sector since 1986, offering an integrated consultancy, testing, and training service for companies and public bodies.

It is a reference point in the field of Medical Devices in Italy. Over the years, the laboratory has expanded its service range to include the cosmetic, pharmaceutical, and consumer goods industries, and has specialised in the validation of controlled environments.

The company has a **highly-trained team that is always up to date**. This allows to tailor the services to the needs of the customer, ensuring data with high scientific value and speed of execution.

Biochem **offers the customer an all-round service** accompanying them from the design of the Medical Device to its marketing and throughout the whole lifetime of the product.

The offer is specific and tailor-made to any type of medical device: **Class I, IIa, IIb, III** (classification in line with Italian legislative decree No. 46 of 24 February 1997), **Devices Composed of Substances** (as defined in EU Regulation 2017/745 - MDR), Finished and semi-finished devices, apparatuses, appliances, reagents, material intended by the manufacturer to be used, alone or in combination, for human beings for one or more specific medical purposes.

#### Services:

- **In vivo and in vitro biocompatibility** testing of Medical Devices
- **Chemical characterisation for biological evaluation and toxicological evaluation** of Extractables and Leachables
- Chemical and microbiological testing for qualitative and quantitative identification of microorganisms and substances and sterility control in line with the European Pharmacopoeia (Ph. Eur.) and the United States Pharmacopoeia (USP)
- Drafting of **BEP, BER, Gap analysis**
- Evaluations and testing for the validation of **FDA reprocessing**
- Validation of pharmaceutical packaging and packaging systems for sterile Medical Devices (ISO 11607)
- Stability of Pharmaceutical and Active Principles and compatibility between Pharmaceuticals and/or Active Principles and Medical Devices.

## Our laboratories • Test'ing

Test'ing specialises in the tests and measurements necessary for certifying and marketing active Medical Devices.

The laboratory is accredited by **ACCREDIA** (Italian System for the Accreditation of Laboratories), in compliance with **UNI CEI EN ISO/IEC 17025:2018** standard. It is a **CBTL**, (Certification Body Testing Laboratory) for the National Certification Body BSI (British Standards Institution), and can ensure that your device is accepted internationally thanks to the CB test report and the CB certification scheme.

Its long experience in the field of Medical Devices guarantees the regulatory compliance and safety of tested devices. Thanks to our state-of-the-art instruments and procedures and our experience in certifying Medical Devices, we ensure accurate and reliable results. With Test'ing, you can count on **technical expertise, short delivery time and reliable results** to meet your safety and compliance needs throughout the certification process.

### Services:

- **Electromagnetic compatibility in line with IEC/EN 60601-1-2**
- **Electrical safety in compliance with IEC EN 60601-1 standard** and particular part 2 standards based on the type of Medical Devices
- Radio testing and measurements on devices with built-in WiFi and Bluetooth modules
- Testing the plastic materials of Medical Devices
- Usability testing and report of the Medical Device
- Validation of medical software
- Risk analysis evaluation
- **CB report for Medical Devices**



## Medical Devices Division • Regulatory consultancy and support services

White Lab specialises in **consultancy services for the certification of Medical Devices** to be marketed internationally. Its all-round services for the compliance and safety of electrically powered and static devices guide companies throughout the whole product certification process in Europe and worldwide. The service starts with the identification of the reference standards for the medical device and the drafting of **technical documents and includes the support for the drafting of audits and the resolution of non-compliances.**

A team of professional technicians follows the customer, collaborating with their technical department both during product development and prototyping and testing phases to check that they comply with reference regulations and to ensure that they can be placed on the market as soon as possible.



### Services:

- **Drafting of technical documents in line with MDR 2017/745**
- Support for drafting the Risk Analysis
- Regulatory strategy definition
- Drafting of **BEP, BER, Gap analysis**
- Drafting of the clinical evaluation report
- Checking the drafting of the Use and Maintenance Manual
- Audit to check system compliance
- **Laboratory testing and measurements management**
- Consultancy for medical certification outside the EU
- **Tailor-made training on the management system and the technical and regulatory aspects**

For info and offers

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## Biochem

Accredited by the Italian System for the Accreditation of Laboratories(**ACCREDIA**), in compliance with **UNI CEI EN ISO/IEC 17025:2018** standard

**GLP Test Facility** for Biocompatibility testing on medical devices and raw materials

## Test'Ing

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**CBTL** (Certification Body Testing Laboratory) for the National Certification Body BSI (British Standards Institution)



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