pH Labs

Add value.
Inspire trust.

Testing services on medical devices

The pH Laboratories' expertise

Medical Device legislation: the state of the art

Today the European Medical Device industry is affected by profound regulatory changes. The EU Regulation 745/2018 (MDR), which came into force in May 2017, imposes a much stricter approach to certification than before, both in terms of general safety and performance requirements as well as in terms of what is mandatory for manufacturers and other market players to ensure a robust justification for bringing their products to the market.

The Regulation also extends compliance requirements to a range of aesthetic products, such as cosmetic contact lenses, fillers, cosmetic prostheses.

Above all, the technical standards relating to biocompatibility have been profoundly modified.

First of all, the ISO 10993 part 1 (rev. 2018) standard adopts a much more Risk Management approach compared with the previous version, more based on the "checklist" approach.

ISO 10993-18:2020 related to chemical characterization assumes in this context a strategic role for the definition of Biological Evaluation Plans of Devices.

pH Laboratories: quality, safety and reliability

Founded in 1982, the pH Laboratories were acquired by TÜV Italia - TÜV SÜD Group in 2013. Our main offices are located in Barberino Tavarnelle (FI) and Tito Scalo (PZ). The laboratories carry out testing activities for Food Safety and Food Contact, as well as in the environmental field. In addition to these sectors there are services in the area of Healthcare, including testing on medical devices and medical gases.

As part of the international network of TÜV SÜD Group laboratories, pH Laboratories have become reliable and acknowledged partners in these areas, gaining experience, competence and reputation for chemical and biological tests (microbiology and molecular biology) accompanied by numerous **accreditations obtained through Accredia** according to ISO 17025 and other international awards.

pH Laboratories testing

We provide services of medical devices testing that cover manufacturer's key needs.

Biocompatibility tests

- Chemical characterization according to ISO 10993-18
- Cytotoxicity according to ISO 10993-5
- Genotoxicity according to ISO 10993-3
- Hemocompatibility according to ISO 10993-4

Microbiology and sterility testing

- Sterility test and validation according to ISO 11737-2
- Bioburden validation and determination according to ISO 11737-1
- Endotoxins (LAL test) according to Pharmacopoeia method D 2.6.14
- Cleaning and reprocessing according to applicable standards

For in vivo testing, the pH Laboratories make use of European partner laboratories.
All methods are performed according to ISO 17025 and soon also according to Good Laboratory Practices (GLP).

The advantages for companies

By availing themselves of pH Laboratories our customers can count on:

- **TÜV SÜD's expertise in the sector**
  TÜV SÜD stands for reliability and quality assurance in the medical world.
- **Competence and reliability of the laboratory technicians**
  Our team is led by Senior Scientists with decades of experience in the healthcare industry and is composed of specialized technicians involved in continuous training. Being part of the TÜV SÜD laboratories network allows pH staff to have a broadened vision on activities and a constant exchange with colleagues working for an organisation with the most vast product experience at an international level.
- **Accreditations**
  The ISO accreditation of the tests by Accredia guarantees that the test processes are carried out in accordance with international standards.
  The laboratory is also acquiring GLP accreditation.
- **A new laboratory at the forefront of infrastructure and environmental standards**
  The new laboratory is conceived and structured according to the state of the art of the ISO and GLP performance requirements. It complies with these requirements down to the smallest detail (presence of pass-boxes, ventilated cabinets).
  The availability of dedicated test lines for medical device testing, as well as being equipped with the most modern instruments, ensures the optimization of workflows, the reliability of the data and the respect of the test times.
- **Ability to develop R&D activities and internal testing methodologies**
  The expertise and professionalism of the pH technicians enable the laboratory to develop more and more efficient testing techniques thanks to a continuous R&D activity.

Our mission and principles

The member Laboratories of the TÜV SÜD Group must maintain the requirements of impartiality and independence to avoid conflict with the Group's status of Notified Body. TÜV SÜD is also engaged in its activity to spread the sector's high level technical, scientific and regulatory culture, through training events, exchange of general technical information to help clients understanding comply with specific legal requirements. Based on TÜV SÜD's mission to "promote progress by protecting people, the environment and assets from the adverse effects of technology", pH Laboratories pursue a policy aimed at favouring in vitro rather than in vivo testing on animals.

Add value. Inspire trust

TÜV SÜD, to which the pH laboratories belong following the acquisition by TÜV Italia, is a premium body in quality, safety and sustainability and provides analysis, testing, inspection, audit, certification and training.

Present in the world with over 1000 locations, it has accreditations in Europe, North and South America, Asia and Africa. It provides objective services that represent tangible value for businesses, consumers and the environment.

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