CEHTRA

Your Specialties, Our Expertise

Medical Devices

Biological Safety

- To guarantee the biocompatibility of materials and substances of medical device

Regulatory Support

- To ensure compliance with regulatory requirements throughout the life cycle of medical devices

Quality Management

- To guarantee regulatory compliance based on regulatory requirements and EN ISO 13485

Chemicals (REACH)

- To ensure that the products that are part of your processes comply with REACh regulations

- Patient safety is at the center of our concerns. Speed up your time-to-market is essential to fulfill this goal.
- Whether you are a legal manufacturer of medical devices, a subcontractor or a supplier, CEHTRA supports you throughout the life cycle of your medical device, from design to post-marketing follow-up, including CE marking.
- We provide our independence and expertise in biological risk assessment to demonstrate the biological safety of your device.
- The transversality of our expertise in sectors such as pharmaceuticals, biocides, cosmetics and chemicals (REACH) enables us to provide you with the most detailed support.
- Our expertise includes the Devices without an intended purpose, the borderline products

Value-added Services

- Global and transversal approach
- Data and bibliographic analysis for Biological Safety
- High level of expertise in toxicology and medical device kept up to date (ISO/EN)
- Training: Regulatory Affairs, Biological Safety, standardization
- Independence from labs
- Benefit/risk Evaluation

Key Sectors

- Biocides
- Chemicals (REACH)
- Cosmetics
- Global Chemicals Notification
- Industrial Hygiene
- **Medical Devices**
- Packaging
- Pharmaceuticals
- Plant Protection
- REACH Authorisation

Key Contact

Pierre-Yves JOYEUX
Head of Medical Devices sector
pierre-yves.joyeux@cehtra.com

Key Services

- Dedicated Support (Régie)
- Endocrine Disruption
- Poison Center Notifications
- Representation Services
- Trainings