CONSULTING
ENGINEERING
REGULATORY AFFAIRS

selenium
MEDICAL

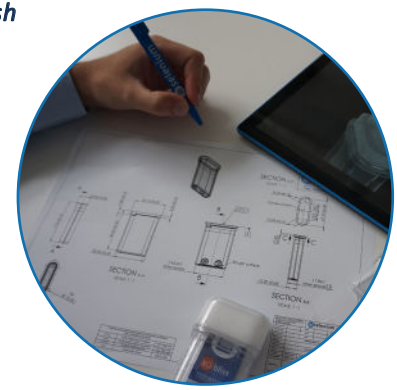
FROM DEVELOPMENT TO CERTIFICATION

Our expertise

Whether you are a start-up or a large company, we support medical device manufacturers at every stage of their project, from development to certification. We offer a customized service, adapted to the specific needs and expectations of each client. Our teams of experts leverage their technical and regulatory expertise, enhanced by our own innovations in packaging and processes, to effectively advise and guide through the healthcare sector's requirements.

Research and Development (products & processes):

Our R&D team brings your concepts to life, based on the functional needs and the requirements of the products or processes you wish to develop.



- Medical devices and accessories design.
- Packaging design.
- Development of special processes.

Manufacturing engineering:

Our team advises you on the feasibility of the technical aspects to take your project through to its production launch.

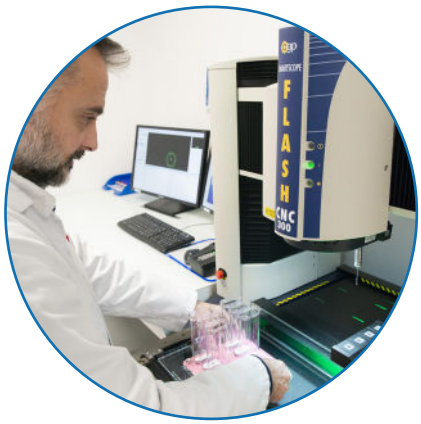
- Technical support: assembling, cleaning, packaging, surface treatment, sterilization methods, optimization of plastic injection part design.
- Creation of specific manufacturing flowcharts for your medical devices.
- Creation of specific production components and tools.
- Definition of packaging: creation of product visuals and labeling in accordance with customer needs and regulations.
- Planning and monitoring of client developments in relation to qualification/validation services.

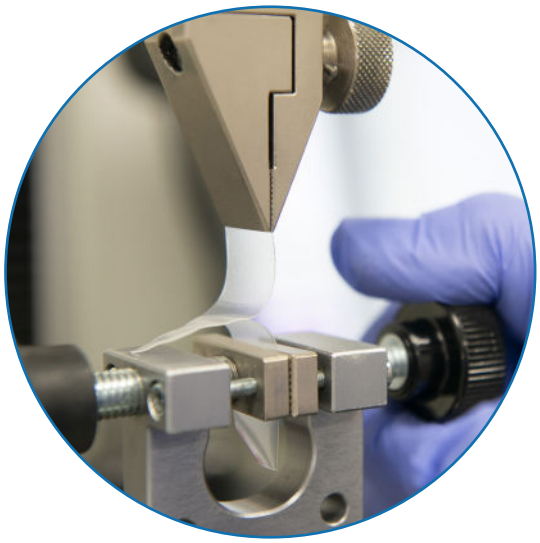
A TURNKEY SUPPORT

Laboratory testing phase:

We conduct a wide range of tests in our laboratories and work with qualified partners to complement our offerings.

Mechanical testing laboratory and characterization of sterile barrier systems	Dimensional measurement laboratory and surface analysis	Microbiological analysis laboratory and other extractable surface residues
▪ Tensile / compression testing. ▪ Peel test for pouches and blisters. ▪ Packaging integrity testing (flexible and rigid packaging). ▪ Aging in climatic chambers. ▪ Transport simulation.	▪ SEM/EDS: Scanning Electron Microscope and Energy Dispersive X-ray Spectroscopy. ▪ 3D measurement machine. ▪ Roughness tester: Surface condition measurement. ▪ Tensiometer: Surface tension measurement (surface energy).	▪ Bioburden ▪ Endotoxins ▪ Biocompatibility ▪ TOC/TIC ▪ Inorganic residues ▪ Particulate residues ▪ Sterility test ▪ Dose audit





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With a deep understanding of health authority requirements, our dedicated teams are committed to ensuring the quality and compliance of your solutions.

Regulatory and compliance support:

We offer customized assistance in the development of technical files and a tailored consulting approach for each device.

- Audit of the Quality Management System and/or manufacturing processes: Implementation of action plans and support.
- Implementation or compliance of the Quality Management System.
- Implementation of control methods.
- Drafting or updating technical files for CE marking or 510(k) submissions.
- Support during certification/inspection audits and responses to non-conformities (NCs).
- Writing standard analyses in the medical device field and their impact on existing products/ processes.
- Assistance in change management.

Validation support:

Our validation experts assist you from the development of your validation strategy to the provision of required deliverables (protocols and reports). With our proprietary validations, we enable you to achieve significant budget savings and reduce time-to-market.

- Development of strategies and creation of validation files for critical processes (final cleaning, single or double barrier packaging, and sterilization).
- Qualification of equipment or production tools (sealing, assembly, injection...) according to Installation, Operational, and Performance Qualification principles (IQ, OQ, and PQ).
- Validation of processes according to Operational and Performance Qualification principles.
- Updating client validation files.
- Assistance in the qualification of clean rooms, implementation of monitoring plans, and risk management.
- Validation of finished sterile products according to PPQ principles.