

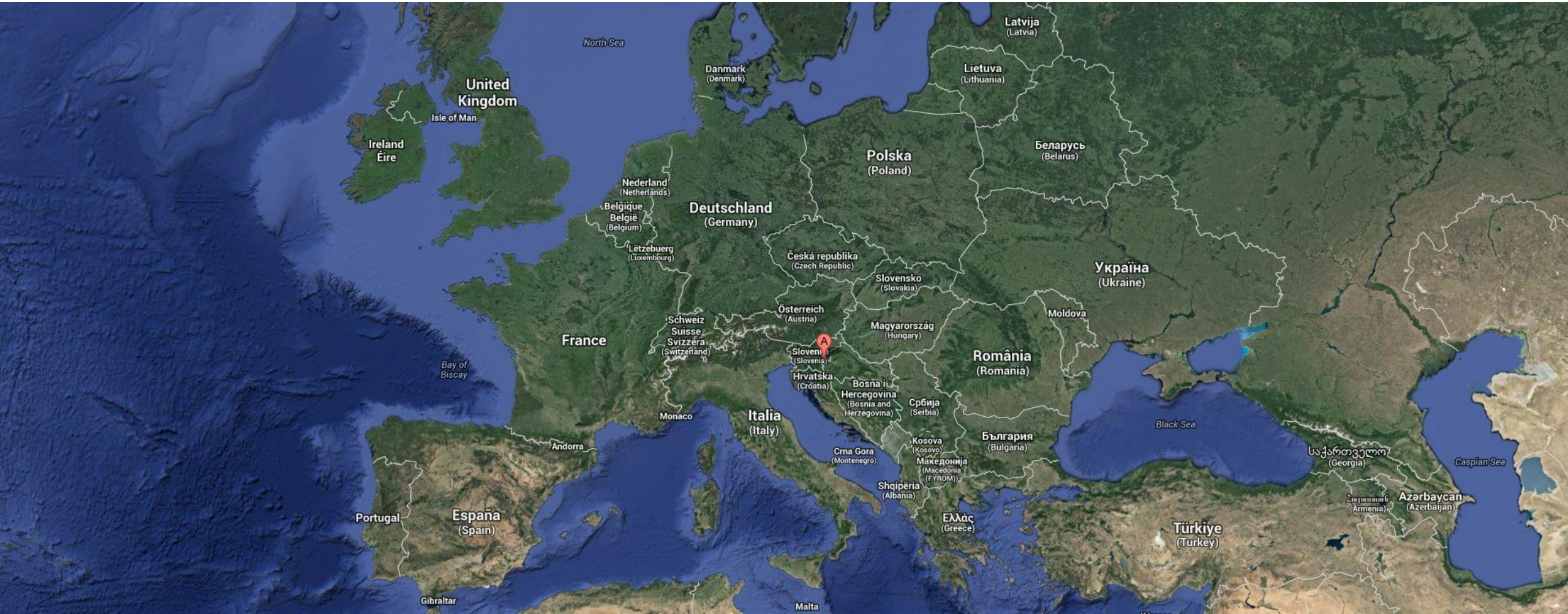


CLEAN AND CLEANING
TECHNOLOGY



Location

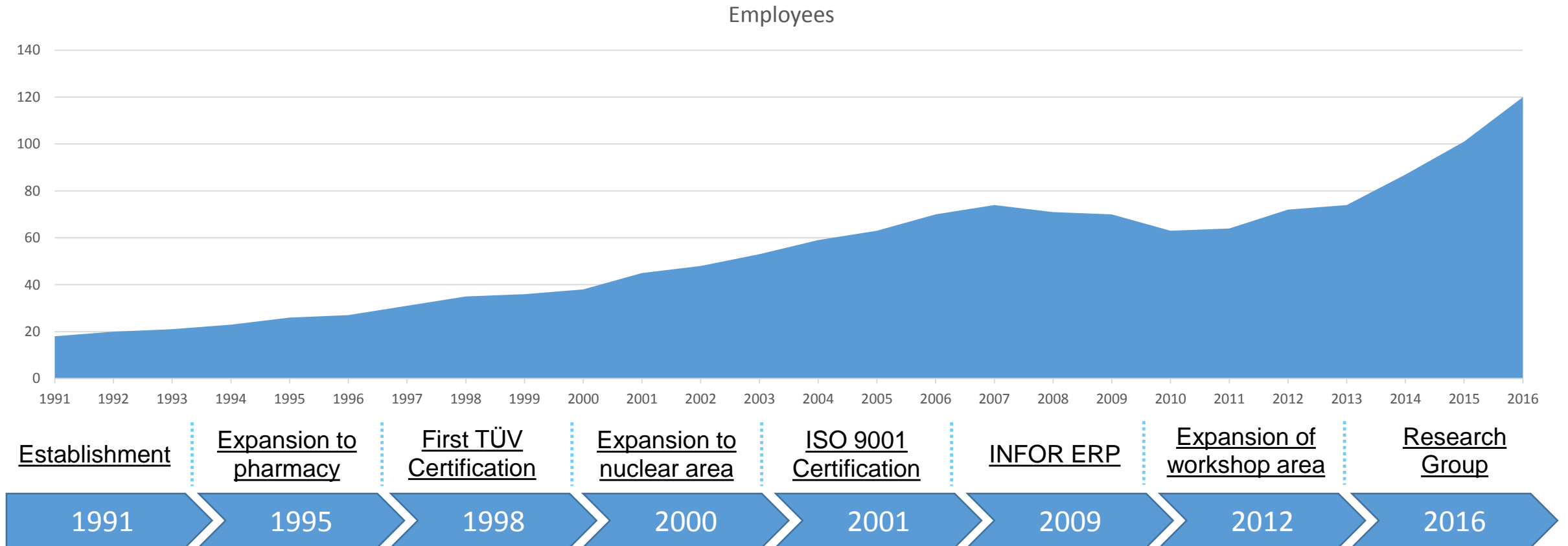
Trubarjeva cesta 5, 8310 Šentjernej, Slovenia





History

Iskra PIO Ltd is a privately owned company with registered office and production facilities in Slovenia. Since we were established in 1991, we have developed into an innovative engineering and manufacturing company with more than 100 customers world wide.





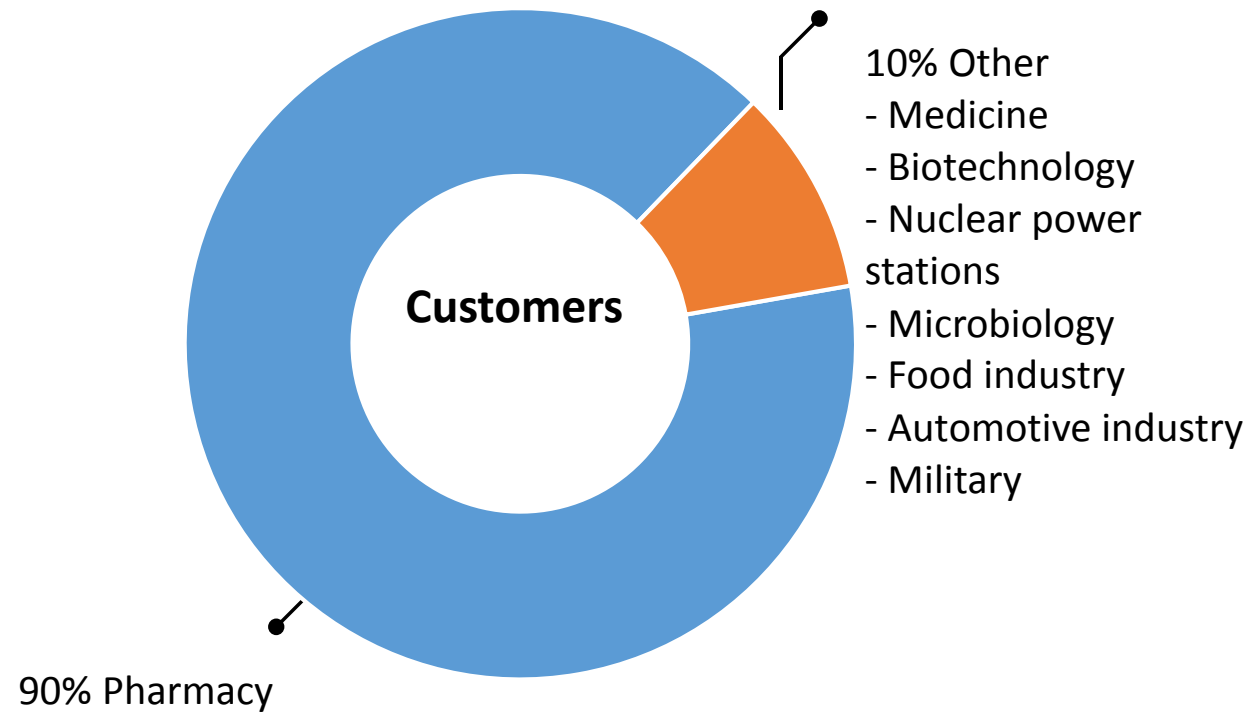
Today



The company's main activity is design, manufacturing, integration, automation and validation of pharmaceutical equipment.

Iskra PIO today:

- No. of employees: 121
- Company area: 4.426 m²
- Share capital: 1.132.627,00 €
- Turnover: 10 mio €
- Export: 52%
- Certificates:
 - ISO 9001:2015 - QMS
 - SIST EN 1127-1:2008 - ATEX
 - SIST EN 1090-2:2008+A1:2012 - Welding





Vision

To be a preferred partner in the supply of more demanding manufacturing and processing equipment for the pharmaceutical industry.

We are customer oriented company with many advantages:

Flexibility

All our equipment is designed according to customer's needs

Innovation

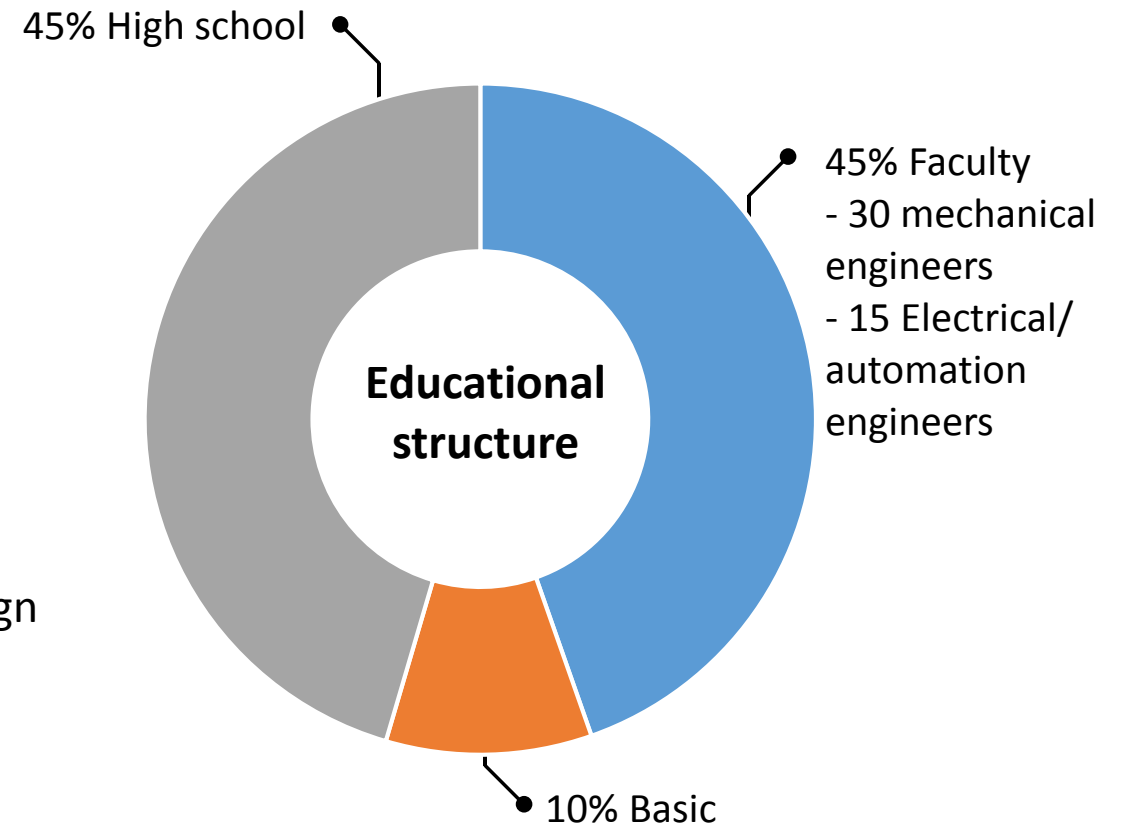
We believe that continuous investments in R&D are right way to success

Experience

In more than 25 years we have learned how to assure best quality and user friendly design

Reliability

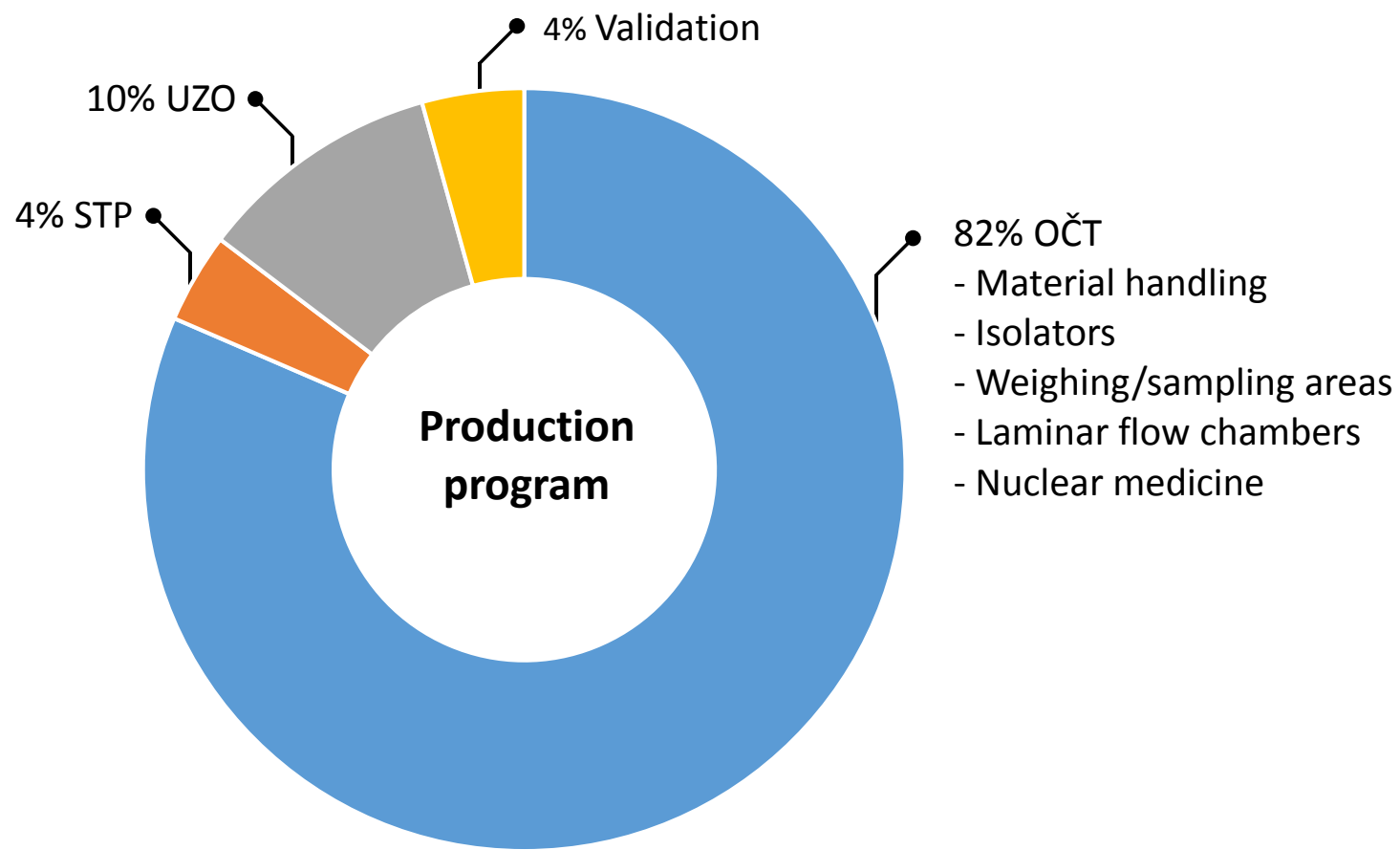
We produce professional equipment and provide 24/7 support to our customers





Production program

The company's production program consists of equipment for clean (OČT) and cleaning technology (UZO). Additional programs comprise of validation and aluminium program (STP).





Laminar flow chambers



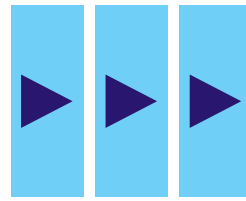
Laminar flow benches – Protective class I, II

- various types
- protection (substance, operator, environment)
- various dimensions
- fit for use in pharmacy, biology, micro-biology, nuclear medicine, oncology,...
- designed and made according to customer demands and needs.

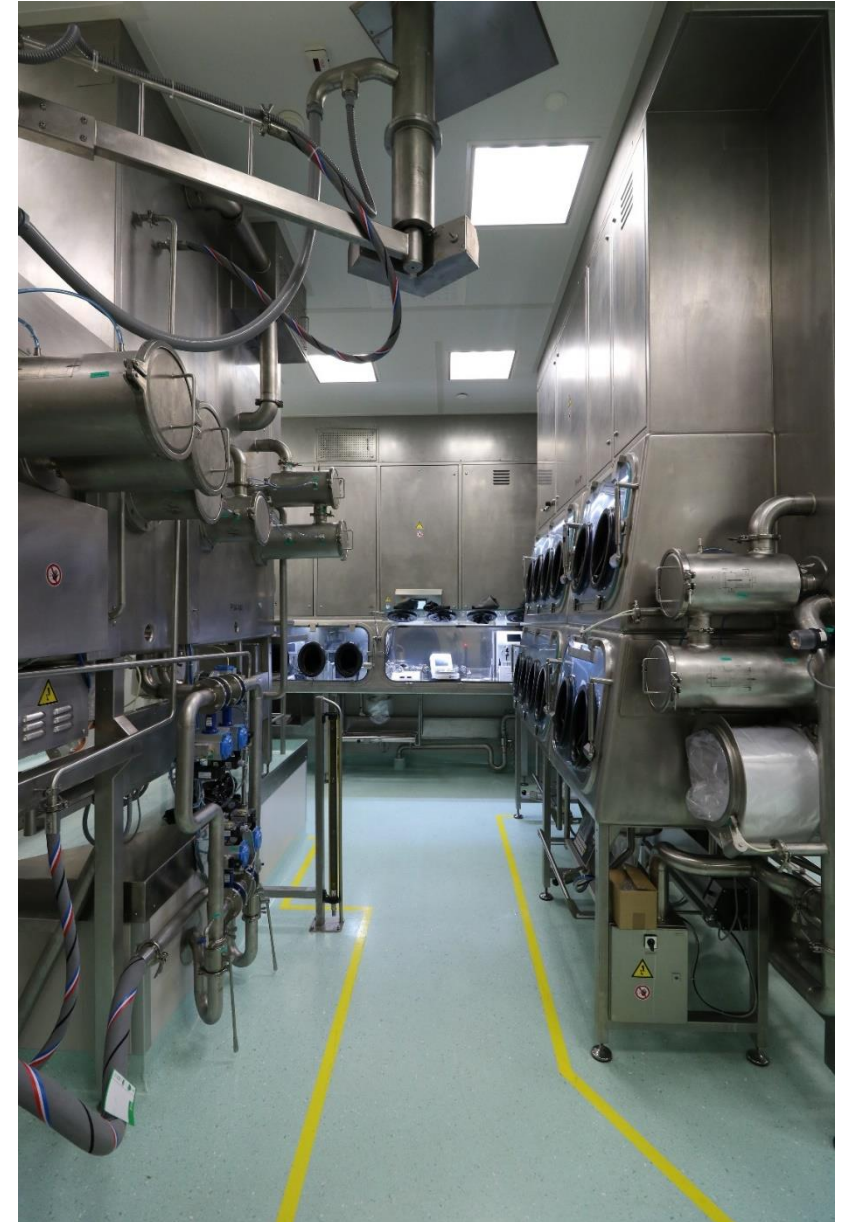




Isolators



- For containment and sterile applications
- Ensure the highest level of protection for the operator, product and environment
- Operation in inert atmosphere (nitrogen)
- ATEX compliant
- Equipment integration: for weighing, sampling, packing, sterility testing, sieving, granulation, coating, safe waste removal, safe filter change, PVC, ALU welding, etc
- Flexible containment

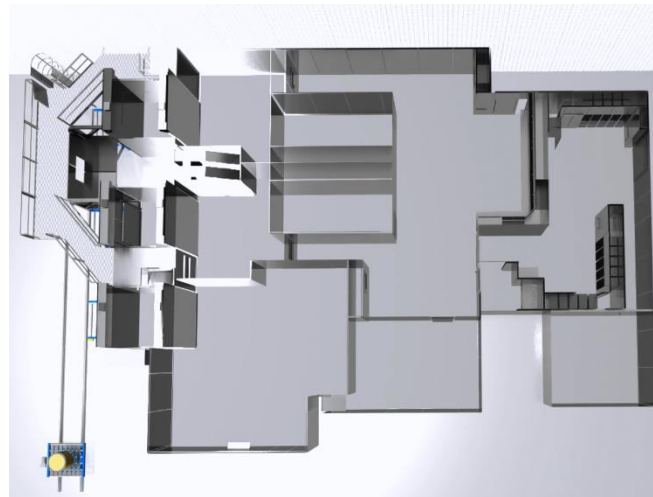
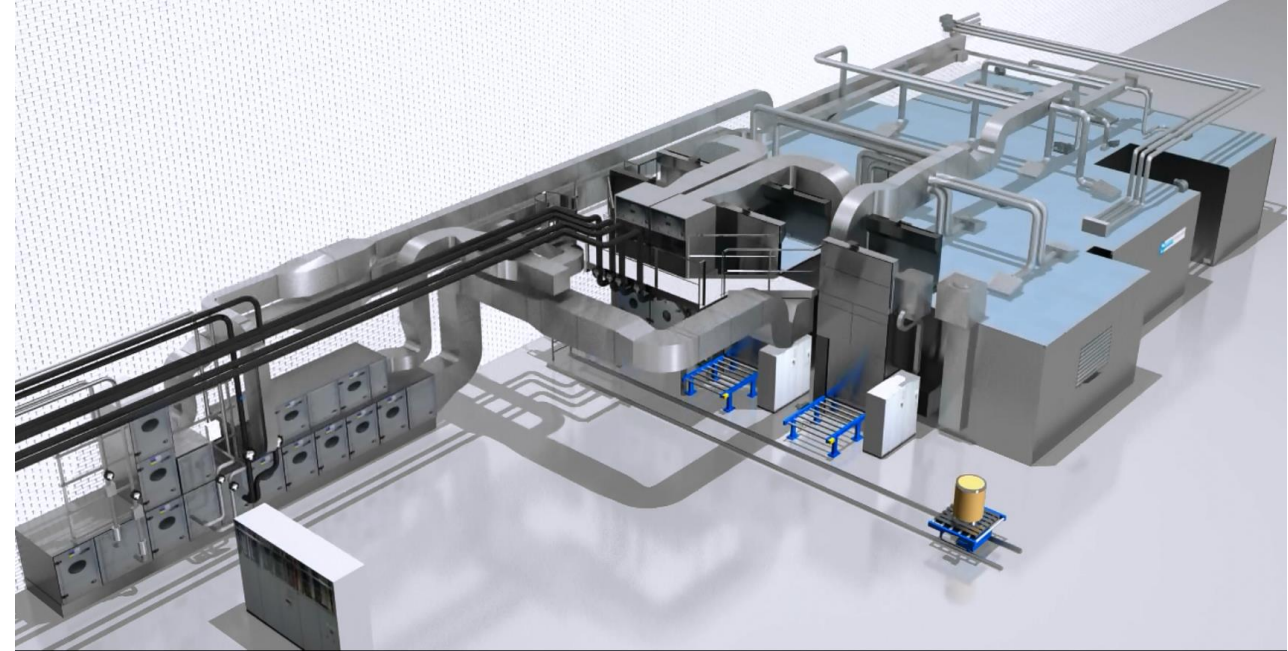




Clean rooms



- Walls (panels), ceilings, windows, doors, floor
- Interlocks, HVAC systems, channels, distributors, filters, installations...
- Implementation of sensors and safety elements
- System control, monitoring and regulation (temperature, pressure,...)





Personal/Material barriers



Barriers serve as a transitional area between the unclean and the clean regime.

- Personal locks
 - Air showers
 - Mist-showers
- Material locks
 - De-dusting cabinets
 - Transfer hatches
 - with filtration (ventilator, filter)
 - sterilization with UV light
 - VHP/H₂O₂ sterilization

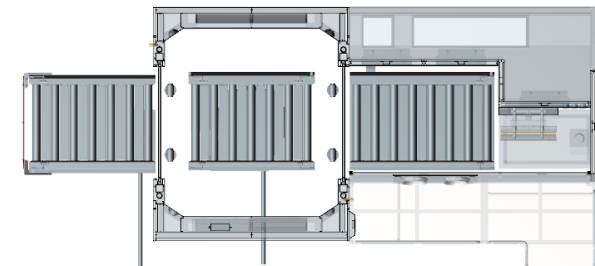
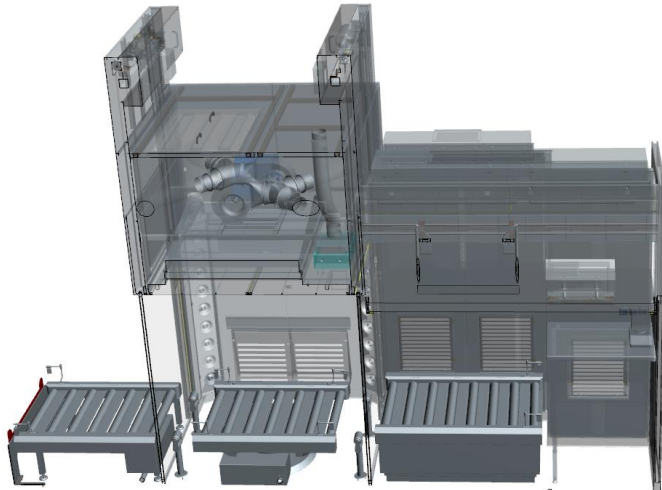
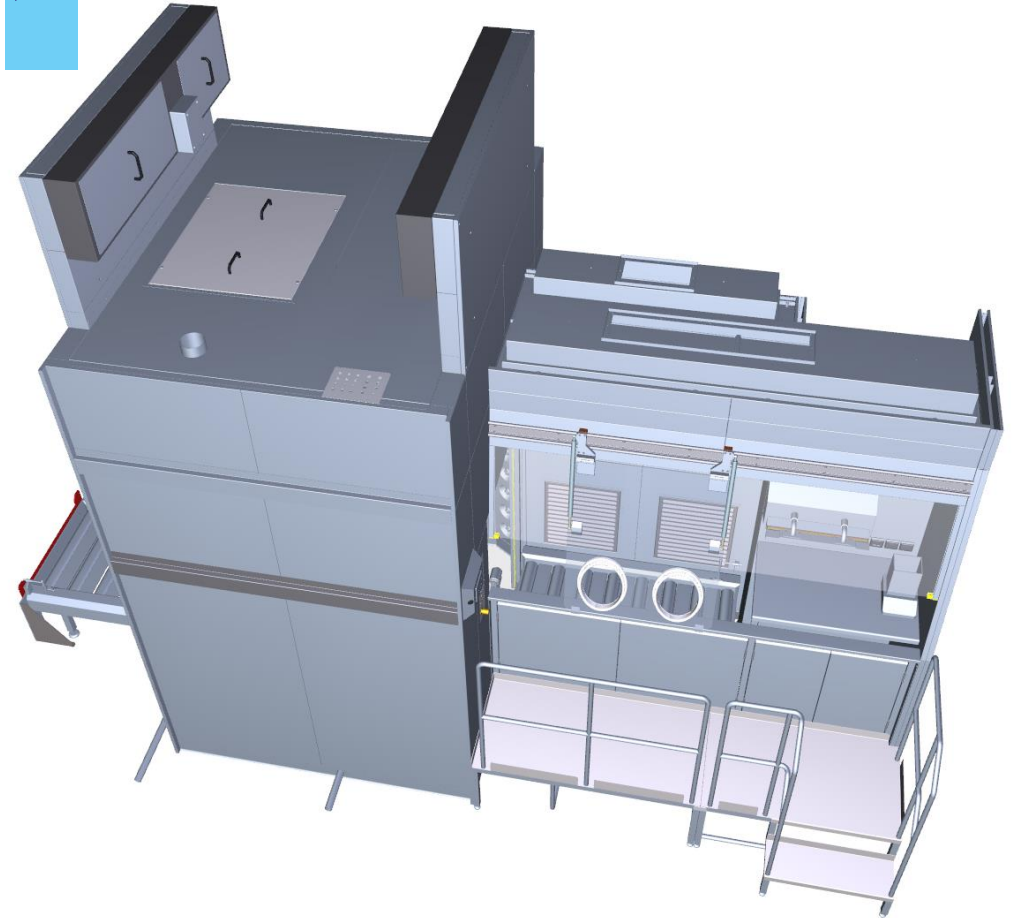




Weighing/Sampling cabins



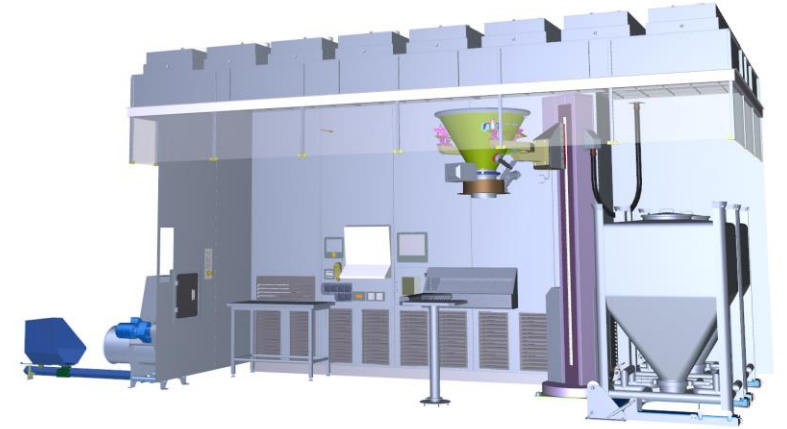
- Sampling cabin with movable shield with gloves for increased safety – OEB 3, OEB4
- Ensures the highest level of protection for the operator
- Provides clean working conditions
- Protects the environment from contamination
- Built-in air locks with interlock function
- Raw materials entering on the pallets
- Fully automated transport system with rotation function





Weighing/Sampling booths

- Unidirectional air flow assures safe weighing – OEB3
- Protection for operator, product and environment
- Clean zone in accordance to ISO 14644
- Vertical or horizontal flow of material
- Controlled and regulated working process
- Fully automatization according to GMP
- Equipment : lifting/tilting device, weighing hopper, compactor for waste, integrated material barrier - de-dusting cabinet, table scales, floor scales, built-in air locks with interlock function, automatic transport ...





UDF, LAF, RABS units

- Made in accordance to GMP regulations and directives
- Protection of substances and processes
- Various dimensions and configurations
- Easy cleaning
- Easy controlled laminar flow
- Simple handling and control
- Different way of built-in execution (ceiling, portable, mobile)

A RABS device is a self-standing device with a vertical laminar air-flow for protection of pharmaceutical process.

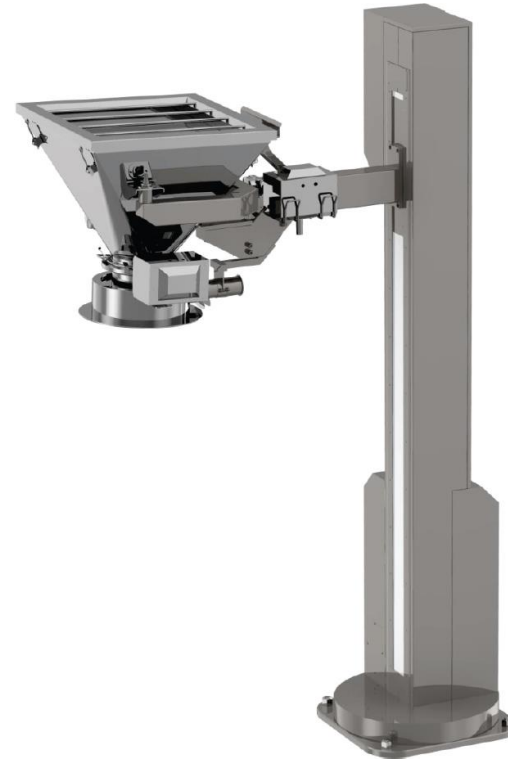




Manipulators

Manipulators are devices that replace manual work.

- Lifts, which enables lifting and rotation
 - Lifts for different containers (IBC, drums...)
 - Hanged lifts
 - Mobile lifts
- Hopper, which is located on the weighing cells
- Weighing platform for containers and barrels
- Trolley for washing the funnel
- Equipment to customer specification





Container mixers

Container mixer is designed for mixing the powder container. It is suitable for mixing of powders, granules or pellet. At the customer's request we develop a mixer according to customer needs.

Mixers types:

- Lab scale
- Pilot mixer (for drums/IBCs)
- Production mixer (Up to 3500 L IBC)
- Lift-blenders





Processing of raw materials



Equipment MHS (Material Handling System)
Preparation of different mixture
One control system to perform all operations: grinding,
seeding, milling, dosing, weighing, ...

Twin lifting system - TLS
Automatic filling line - AFL
Automatic weighing line - AWL





Weighing systems

Weighing systems designed for integration to the dedicated environment – Capacity 200 g – 1500 kg

- Isolator weighing scales - patented
- Weighing funnel
- Weighing platforms for IBCs
- Bag charging systems
- Automatic weighing line





Drying chambers

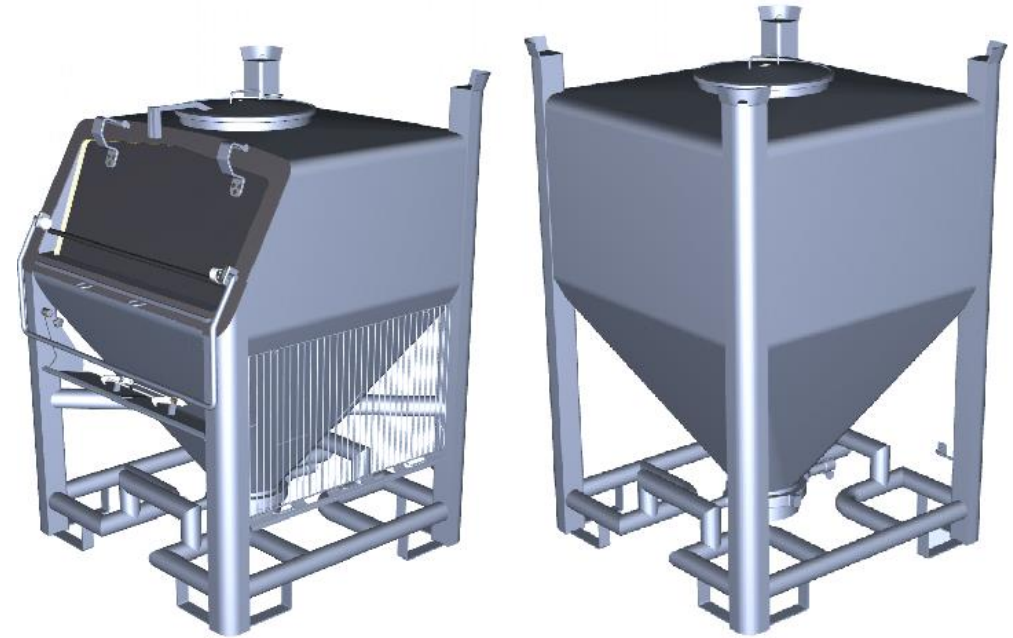
- Tray dryers
 - ATEX execution 2G3D
 - Air humidity: 1 - 100 g/kg
 - Temperature: 20 - 80 °C
- Drying chamber for washed equipment
- Washing and drying trolleys





Other pharmaceutical equipment

- Containers – Various dimensions
- Solution preparation vessels
- Docking stations
- Working tables
- Compactors for packaging waste
- ...





Cleaning technology

EQUIPEMENT FOR ULTRASONIC CLEANING

- ultrasonic cleaners,
 - For tablet punches, sieve and other equipment
 - System with one tank
 - System with multiple tanks
 - With automatic transport

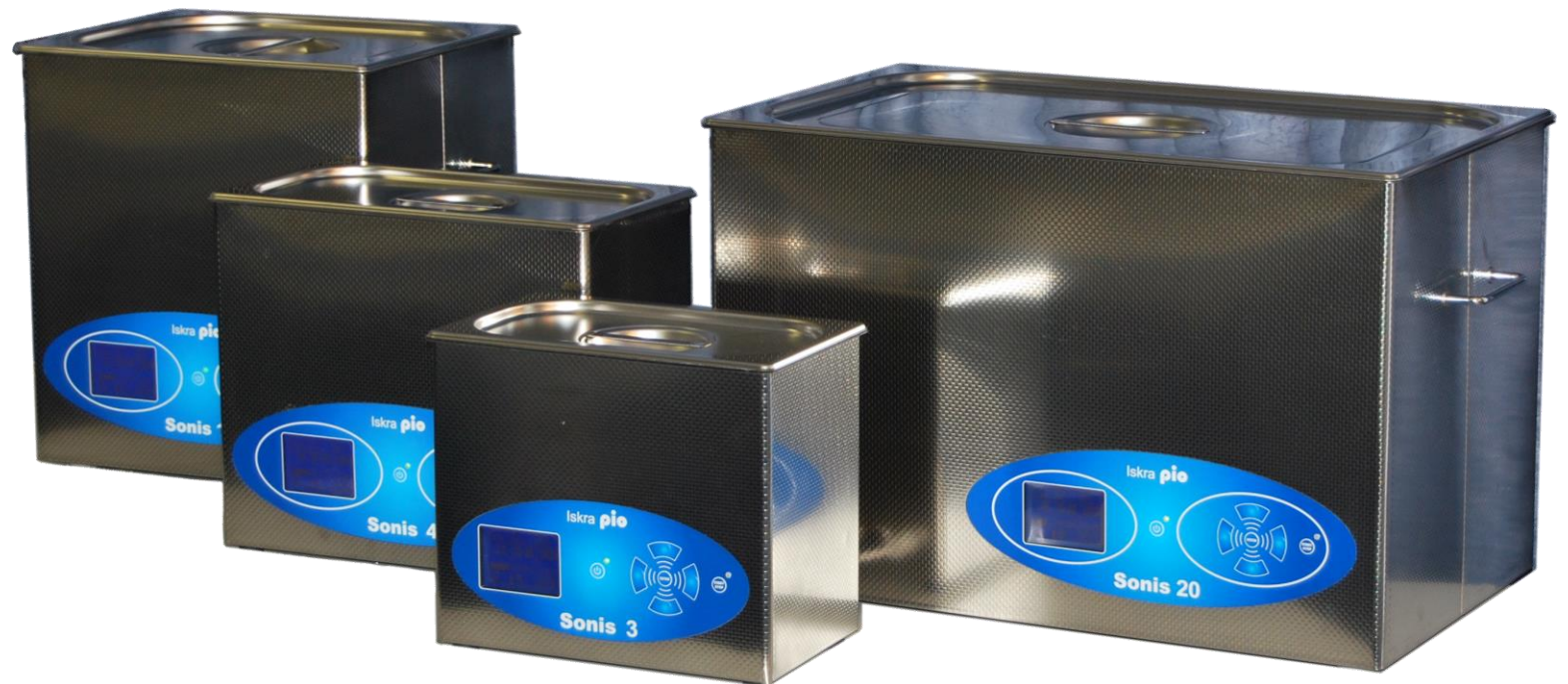
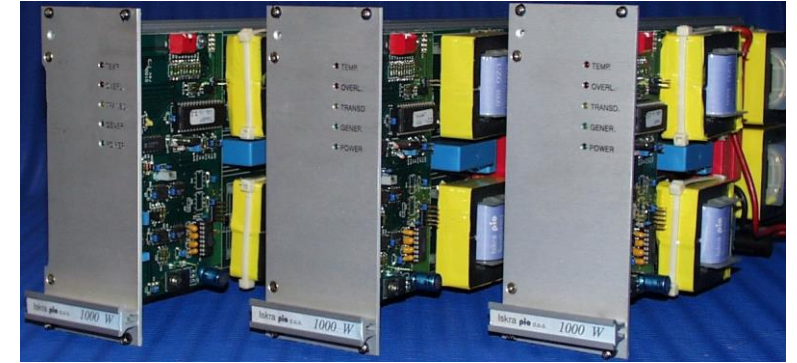




Cleaning technology

EQUIPEMENT FOR ULTRASONIC CLEANING

- Standard ultrasonic cleaners
 - various dimensions (3, 4, 10, 20 and 50 liters),
 - working frequency 30 kHz and 40 kHz,
 - additional equipment (covers, glass holders, metal mesh, ...),
 - cleaning measurements,
- US generators,
- converters,
- additional equipment,
- etc...

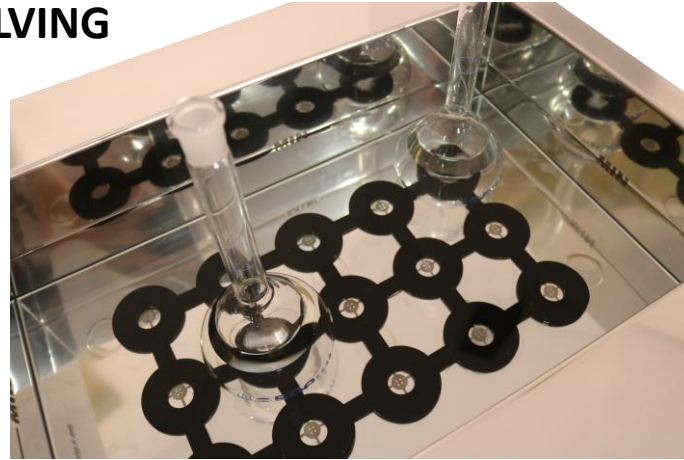




Cleaning technology

EQUIPEMENT FOR ULTRASONIC DISSOLVING

- ultrasonic baths with mixers
 - for dissolving the tablets
 - various dimensions
 - working frequency 30 kHz





Cleaning technology

Military program

- Special vehicle
 - destined for cleaning and decontamination of respiratory protective masks.





Cleaning technology

Military program

- Special containers
 - Mobile Radiological Laboratory.





Cleaning technology

Military program

- Special containers
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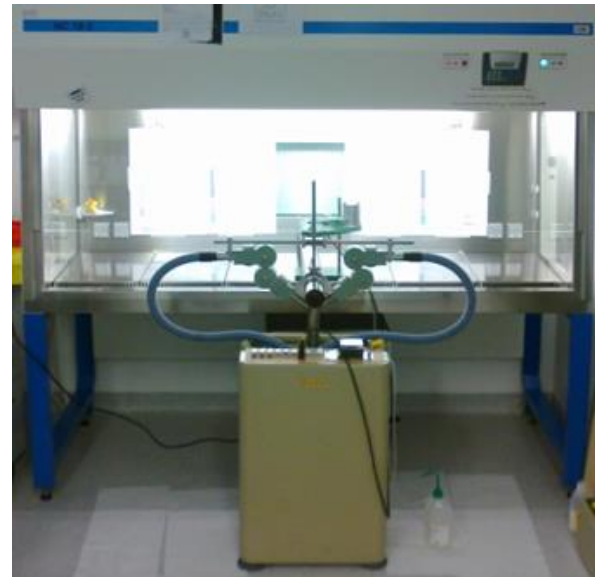




Validations

Validation measurements in clean room areas and of equipment for clean and safe working conditions.

- Particle counting, room classification
- Airflow volumes, air change rates
- Airflow velocity measurements
- Filter in place integrity test
- KI-DISCUS test
- OEL level test
- Temperature test
- Relative humidity test
- Room pressurization test
- Visual smoke test
- Recovery time test
- Light level test
- Noise level test



References

Iskra Pio has been a reliable partner to more than 100 businesses and organizations in Europe, Africa and Russia.





Contact

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