



Sterilization Services

Protect to perform.

Sterilization & Microbiological Monitoring – Consulting from start to submission.

Sterilization services, integrated microbiological monitoring and validation support aligned with international regulatory requirements.

Our Services



Validation & Regulatory Support for Sterilization

- Turnkey validation packages
- Requalification and change impact assessments
- Clear, regulator-friendly reporting formats
- Inspection and audit support



Microbiological Monitoring & Endotoxin Testing

- Bioburden determination and routine testing
- Microorganism identification
- Trend analysis and excursion management
- Support for microbial risk assessments



Sterilization Consulting and Execution

- Validation of radiation sterilization methods (Gamma & X-Ray)
- Dose establishment and routine dose audits
- Steam & EtO sterilization validation support
- Product packaging service (ISO7)



Why FRÜH?

- Proven expertise in radiation sterilization and microbial control
- Well-established certified partner network
- Structured documentation supporting regulatory submissions
- Experienced support during audits and inspections

Protect to perform

Our services are planned, executed, and documented with a clear focus on compliance and traceability.

Our Standards

- Support aligned with: EN 556-1,
- EN ISO 11137 (radiation),
- EN ISO 17665 (steam),
- EN ISO 11135 (EtO),
- ISO 11737-1 (bioburden),
- ISO 11737-2 (tests of sterility),
- ISO 11737-3 (endotoxin).

One point of contact. End-to-end coordination.

Scan the QR code to talk to our sales experts.

