



Because every patient's
safety begins in a cleanroom.





WHO WE ARE

Contamination Control Specialists

Rigel is an Italian company specializing in contamination control for critical environments in pharmaceutical, life sciences and semiconductor manufacturing. Born from the integration of Ascotec (instrumentation distribution), CTP System (GMP consulting) and CNR (public research), Rigel combines scientific rigor, technological expertise and regulatory competence in a single ecosystem covering the entire environmental monitoring lifecycle.

From instrumentation to accredited calibration, from monitoring software to technical consulting, Rigel works with pharmaceutical manufacturers to transform environmental data from a compliance record into a strategic asset.



Founded 2008

Rome, Italy

Europe · Middle East · North Africa · Australia



ACCREDIA n° 01837

ISO/IEC 17025:2017

Accredited Calibration Laboratory



End-to-end ecosystem

Instrumentation · Software

Calibration · Consulting · 24/7 Support



Sectors served

Pharma · Healthcare

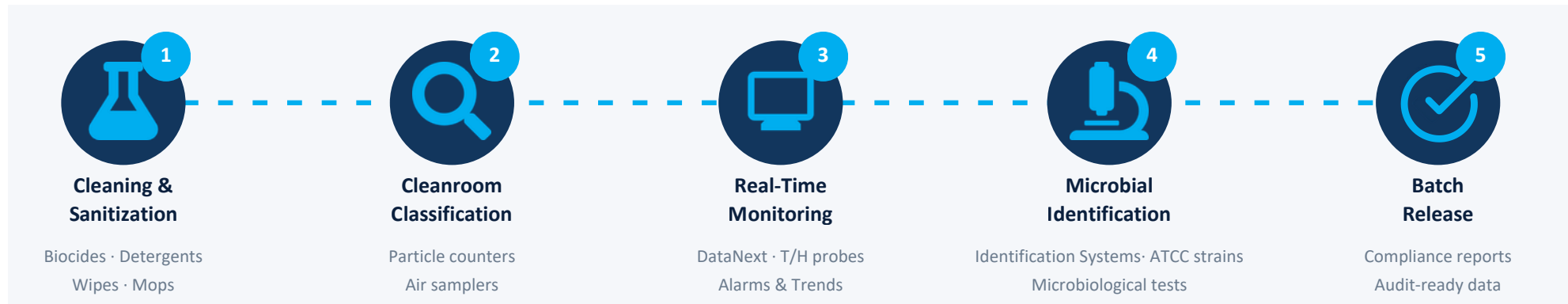
Defense · Aerospace · Semiconductors



ECOSYSTEM OVERVIEW

Cleanroom compliance assurance

From cleanroom sanitization to batch release — one partner, end-to-end.



ONE PARTNER · ONE ECOSYSTEM · FULL COMPLIANCE LIFECYCLE



Training & Education

On-site and remote programs
Annex 1, CCS, best practices



Specialist Consulting

System assessment and co-design
Regulatory support



After-Sales & Support

24/7 technical assistance
Preventive maintenance



Calibration & Validation

ACCREDIA ISO 17025
IQ · OQ · PQ packages and Full GAMP 5
Validation



WHY RIGEL

Your end-to-end contamination control partner



Instrumentation

Particle counters, microbial samplers, HEPA filter testing.
Proprietary technology for continuous GMP monitoring.



Monitoring Systems

DataNext® integrated platform with SCADA, 21 CFR Part 11 and Annex 11 compliance, real-time data integrity.



Accredited Calibration

ACCREDIA lab n° 01837, ISO/IEC 17025:2017.
Four measurands: particle size, counting efficiency, size resolution, flow rate.



Consulting & Support

Technical assessment, co-design, IQ/OQ/PQ validation, Annex 1 training and 24/7 after-sales support.

From assessment to ongoing support. One partner. One ecosystem. Full traceability.



PARTICLE COUNTERS

Aerix Remote 3001 / 3101



Remote Airborne Particle Counter

Engineered for reliable, standards-compliant airborne particle measurement in the most demanding controlled environments. Sealed Class 1 laser engine, stable critical-orifice flow control, and robust industrial communication interfaces ensure consistent, uninterrupted performance during continuous operation.

Available in Modbus RTU (RS-485) for legacy compatibility and Modbus TCP/IP with PoE for modern, future-ready architectures.

Key specifications

- ✓ Dual-channel measurement @ 0.5 and 5.0 μm
- ✓ 1.0 CFM (28.3 L/min) flow rate with critical-orifice stability
- ✓ ISO 21501-4 and ISO 14644 fully compliant
- ✓ Stainless-steel (304) cleanroom-ready enclosure
- ✓ 65,000-record rotating buffer memory
- ✓ External vacuum > 500 mBar required
- ✓ 2-year limited warranty

Applications

Aseptic manufacturing

BFS / ATMP

Isolators / RABS

Distributed EMS

Fill-finish lines

Lyophilization



PARTICLE COUNTERS

Aerix Portable 5001



Portable Airborne Particle Counter

Aerix Portable 5001 is a Next Generation portable particle counter, delivering 6-channel simultaneous measurement @100 LPM — for maximum operational flexibility across ISO 14644 classification scenarios.

Touchscreen interface, integrated printer and internal data storage enable fully autonomous field operation. Rechargeable battery with AC backup ensures uninterrupted sessions across multiple rooms.

Key specifications

- ✓ 6 channels simultaneous measurement
- ✓ Flow rate · 100 LPM
- ✓ ISO 21501-4 and ISO 14644 fully compliant
- ✓ Stainless-steel (316) cleanroom-ready enclosure
- ✓ 10,000,000 data record internal storage
- ✓ 21 CFR Part 11 compliant audit trail and users privileges configuration
- ✓ 2-year limited warranty

Applications

Aseptic manufacturing

BFS / ATMP

Isolators / RABS

Distributed EMS

Fill-finish lines

Lyophilization



PARTICLE COUNTERS

Aerix Remote+ 4101



Remote Particle Counter with Built-In Pump

Designed for controlled environments where no external vacuum source is available. Combines a sealed laser diode optical engine with a built-in sampling pump delivering stable 1.0 CFM flow.

Up to 4 configurable particle size channels, seamless integration with DataNext®, SCADA and modern EMS platforms.

Available in Modbus RTU (RS-485) and Modbus TCP/IP with PoE++ for single-cable deployment.

Key specifications

- ✓ Up to 4 channels: 0.3, 0.5, 0.7, 1.0, 3.0, 5.0, 10.0 μm
- ✓ Built-in sampling pump — no external vacuum needed
- ✓ 1.0 CFM (28.3 L/min) flow rate
- ✓ 4–20 mA flexible analog output per channel
- ✓ ISO 21501-4 and JIS B 9921 compliant
- ✓ PoE++ (802.3bt) — single cable for power and data
- ✓ Compact: 181 × 110 × 190 mm, 3.4 kg

Applications

Pharma cleanrooms

Isolators / RABS

Hospital ORs

Distributed EMS

Building automation

Sterile compounding



MICROBIAL AIR SAMPLERS

HEBAS Impaction Head



High Efficiency Biological Air Sampler

Detects potential contamination from viable particles with 98.9% microbiological efficiency (certified per ISO 14698-1 Annex B). The proprietary HEBAS head geometry precisely directs sample air onto culture media while reducing micro-organism stress upon impact.

With the optional IVS (Internal Vacuum Source) unit, the HEBAS provides fully self-contained sampling for isolators and RABS, with exhaust air filtered to ISO 3 compliance.

Key specifications

- ✓ 98.9% microbiological efficiency (vs Casella reference)
- ✓ D50 physical cut-off: 0.8 μm · D100: 1.1 μm
- ✓ 1.0 CFM (28.3 L/min) \pm 5% sample flow
- ✓ AISI 316L stainless steel · fully autoclavable
- ✓ Magnetic coupling — easy sanitization
- ✓ Standard 90 mm Petri dishes
- ✓ IVS unit: brushless pump, mass flow meter, ISO 3 exhaust

Applications

Aseptic manufacturing

Isolators / RABS

Grade A/B areas

Biosafety cabinets

Clean utilities

Fill-finish



HEPA FILTER TESTING

Complete integrity testing instrumentation

A full suite of instruments for HEPA/ULPA filter leak testing and airflow visualization, all compliant with ISO 14644-3:2019.



RI7002

Digital Photometer

Light scattering method for real-time HEPA filter integrity detection. 3.5" LCD base unit + 2.8" LCD scanning probe for line-of-sight reading. Built-in thermal printer. Tests cleanrooms, laminar flow hoods, safety cabinets, isolators, RABS.

ISO 14644-3 · 0.0001–100% concentration



RI8401

Thermal Aerosol Generator

Smallest and lightest thermal aerosol generator on the market. Up to 8 hours continuous operation. Compatible with PAO, DEHS, Emery, Ondina oils. Remote control operation (optional). Starts generating at 0.35 bar.

ISO 14644-3 · 500–70,000 CFM · 1 L tank · 8.9 kg



RI8201

Laskin Nozzle Aerosol Generator

All-in-one unit with integrated compressor. Laskin nozzle cold atomization, ideal for small and medium areas. Stainless-steel construction with individual nozzle control and 3" sanitary fitting outlet.

ISO 14644-3 · 50–2,000 CFM · 2 L tank · 16.8 kg



RI8303

Portable Aerosol Generator

Portable and versatile Laskin nozzle generator for small-to-medium areas. 6 individually controlled nozzles, large 5 L tank, rugged aluminum casing. Optimal for RABS, isolators and safety cabinets.

ISO 14644-3 · up to 8,000 CFM · 5 L tank · 8.5 kg



ENVIRONMENTAL MONITORING

DataNext® – Integrated Environmental Monitoring System



Open-architecture distributed system for continuous monitoring of all environmental parameters required by GMP and ISO standards. Multi-instrument integration with real-time alarm assessment, histogram-based trend analysis and statistical strategies compliant with ISO 14644-2:2015.

The central cabinet integrates power supply, PLC-based electronics, and manifold section for continuous vacuum supply. Scalable from single-server to redundant multi-client architectures.

21 CFR Part 11

EU GMP Annex 11

SCADA

PLC architecture

Redundant servers

GAMP 5

ALCOA+

Histogram trends

ISO 14644-2

Monitored parameters

✓ Continuous airborne particle concentration

✓ Viable airborne particle (microbial)

✓ Temperature & humidity

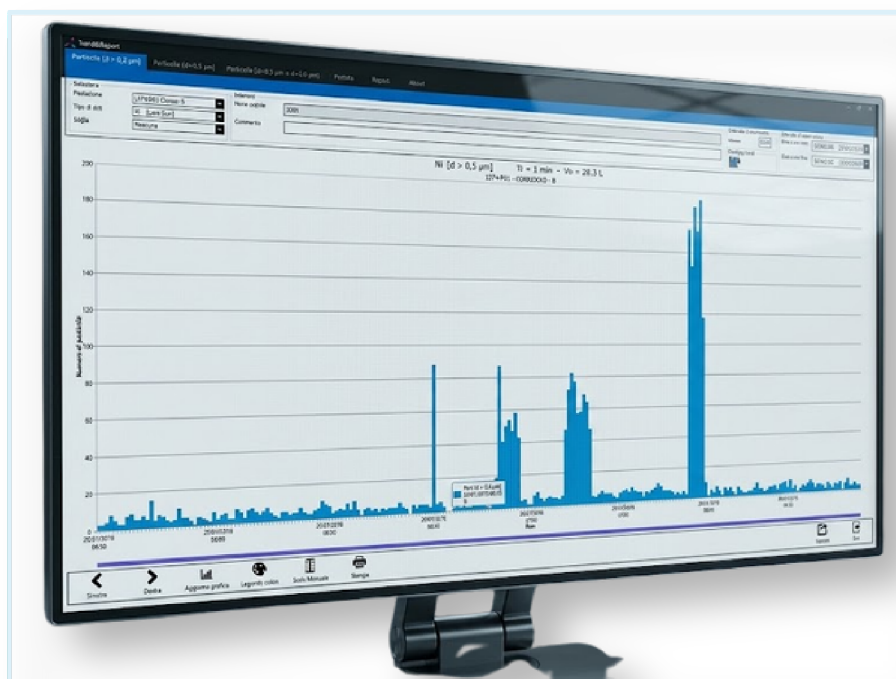
✓ Air velocity & differential pressure

✓ Real-time viable particle monitoring



SOFTWARE PLATFORM

SCADA software for environmental monitoring



Patented trend analysis - TAU

First EMS to use histogram-based display for particle concentration trends.
Statistical strategies per ISO 14644-2:2015 built in and Patented TAU algorithms

The SCADA platform is built on a standard architecture fully compliant with 21 CFR Part 11 and EU GMP Annex 11, ensuring regulatory readiness from day one. Scalable from a single-server deployment on a physical machine to complex architectures with redundant servers, multiple client stations, and virtual environments. Complete audit trail, electronic signatures, and ALCOA+ data integrity are built into the core platform.



Flexible architecture

Single server, redundant, physical or virtual machines



21 CFR Part 11 / Annex 11

Audit trail, electronic signatures, access control



System integration

BMS, EMS, SCADA, MES, LIMS connectivity via OPC-UA



ALCOA+ data integrity

Attributable, legible, contemporaneous, original, accurate



LAB & CONSUMABLES

Cleaning, sampling & reference materials



Cleanroom Garnelements

Sterile and non-sterile garments for controlled environments. Coveralls, hoods, shoe covers and gloves designed for Grade A through D classification areas, with validated packaging for aseptic handling.



GMP-Compliant Wipes & Mops

Pre-saturated wipes, VertiClean MAX mop systems from Contec. Mission-critical cleaning for Grade A through D environments.



Copan Swabs

Surface sampling swabs for environmental monitoring and contamination detection. Validated collection and transport systems for QC microbiology.



Biocides & Cleaning Agents

Complete cleaning product lines for pharmaceutical cleanrooms. Validated detergents from Borer Chemie AG with technical support for cleaning validation.



LAB & CONSUMABLES

Culture media & microbial identification



Ready-to-Use Plates

Pre-poured culture plates for environmental monitoring. Annex 1 compliant options for Grade A through D areas. Consistent quality, reduced preparation time.



Ready-to-Use Bottled Media

Pre-prepared bottled culture media for QC microbiology. Sterility-tested, lot-certified, ready for immediate laboratory use.



Biolog Microbial Identification

Automated identification systems for bacteria, yeasts and fungi. Database-driven phenotypic characterization for environmental monitoring isolates.



ATCC® Derived Strains

Microbiologics certified reference strains for QC testing. Ready-to-use formats for performance testing and method validation.



SERVICE & SUPPORT

Your system runs. Your data holds. Your team is supported.



Accredited Calibration

- ✓ ACCREDIA laboratory n° 01837
- ✓ ISO/IEC 17025:2017 compliance
- ✓ 4 measurands: particle size, counting efficiency, size resolution, sampling flow rate
- ✓ International recognition for cross-border operations
- ✓ Recommended annually per ISO 21501-4



Technical Consulting

- ✓ System assessment and co-design
- ✓ Contamination Control Strategy (CCS)
- ✓ IQ/OQ/PQ validation packages
- ✓ EU GMP Annex 1 training courses
- ✓ Regulatory support for FDA/EMA audits
- ✓ GAMP 5 documentation packages



After-Sales Support 24/7

- ✓ Dedicated EMS support team
- ✓ 24/7 business continuity guarantee
- ✓ Remote diagnostics and intervention
- ✓ Preventive maintenance programs
- ✓ Spare parts and field service
- ✓ Software updates and patches



CERTIFICATIONS & GLOBAL PRESENCE

Standards compliance and worldwide reach



Standards & Certifications

Instrument standards

ISO 21501-4

ISO 14644

ISO 14698-1

JIS B 9921

Regulatory compliance

EU GMP Annex 1

21 CFR Part 11

EU GMP Annex 11

GAMP 5

Data & quality

ALCOA+

ISO/IEC 17025

ACCREDIA n° 01837

EcoVadis

Global presence and Subsidiaries



Rigel USA

TechPlace, 74 Orion St,
Brunswick, ME 04011, United States

Rigel France (Orion)

5 Avenue de la République,
69160 Tassin-la-Demi-Lune, France



Talk to a specialist.

Schedule a technical conversation to understand whether our solutions are the right fit for your environment and your system architecture.

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