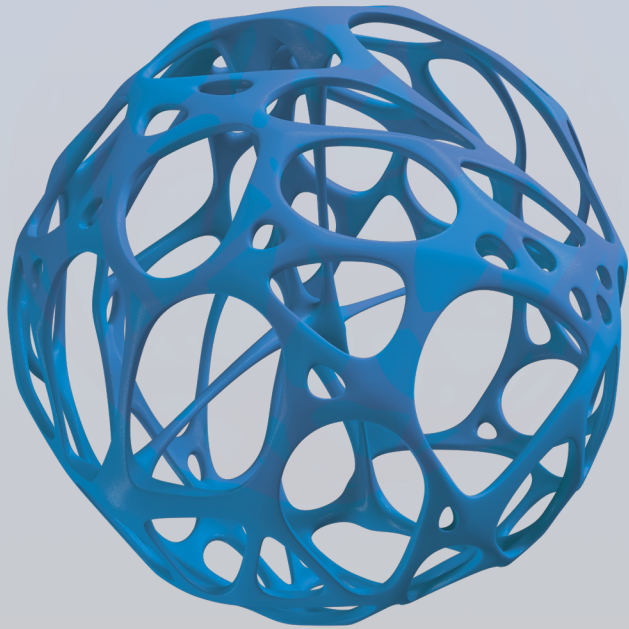


# TWO LEADERS, ONE GOAL

Optimize Your Contamination  
Control Strategy

MERCK



**Millipore®**

Preparation, Separation,  
Filtration & Monitoring Products

# TWO LEADERS, ONE GOAL

Merck and Novatek International team up to monitor contamination and enhance environmental monitoring in the pharmaceutical industry

Automation and digitalization are set to transform the pharmaceutical industry. That's why Merck and Novatek, two global leaders in environmental monitoring (EM) technology, are now partnering to develop solutions that help pharmaceutical companies automate their microbiology workflows and transfer their data into useful information to make real time quality decisions.

Specifically adapted for automation and seamless integration, **Merck's ICR/ICR+** prelabeled culture media plates and swabs, reliable and validated **MAS-100™ microbial air samplers** and **Novatek's compliant EM platform** will allow manufacturers to track and monitor microbial contamination efficiently using the combined expertise of Merck and Novatek in contamination control.

# WHAT IT MEANS FOR YOU...

## Leveraging the Expertise of Two Global Leaders in Environmental Monitoring.

As a leading global supplier of innovative life science products, **Merck** offers hardware and consumables that make microbiological quality control (QC) simpler, faster, and safer. In environmental monitoring, Merck maintains a full portfolio of GMP-compliant solutions for microbial air, surface and personnel monitoring in cleanrooms and isolators, including its proven line of **MAS-100® microbial air samplers** and **ICR/ICR+ culture media**. For optimized workflows in isolators, there are specific solutions (**IsoBag™** and **MAS-100® Iso line**).

### ICR/ICR+ culture media plates

- Excellent recoveries for a broad spectrum of aerobes & anaerobes
- Autoclaved, aseptically filled, triple-bagged, and gamma-irradiated
- Designed to minimize cross contamination caused by handling
- Recovery rates maintained even after strong dehydration in air sampling
- Efficient disinfectant residue neutralization to maintain growth promotion



### MAS-100® microbial air samplers

- Excellent Biological and Physical Collection Efficiencies
- Independently validated with ICR media acc. to ISO 14698 (EN 17141)
- Easy to decontaminate
- Minimal disturbances of unidirectional air flow
- High flow rate accuracy
- Available with HEPA Exhaust filter
- Excellent recoveries of microbes
- Designed to minimize cross contamination caused by handling

# MERCK

Novatek International produces regulatory compliant software solutions for the pharmaceutical industry that reduces risk, contributes to product quality, and ensures manufacturing excellence. With hundreds of clients and thousands of users worldwide, the **Novatek Environmental Monitoring (EM) Software Solution** is an industry-proven standard with 25 years of use in managing controlled environments. From years of assimilating user specifications and regulatory requirements, Novatek's solution has evolved into a powerful, business-ready and compliant platform designed to evaluate, manage, trend, and reduce the contamination and regulatory risks associated with everyday environmental monitoring.



Preview Report

NOVATEK

Quarterly Recovery Rate Report

Classification	Q1 (%)			Q2 (%)			Q3 (%)			Q4 (%)			Annual Rate	
	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC		
ISO 14644	2.00	2.00	1.81	2.19	2.00	1.81	2.00	2.00	1.81	2.00	1.81	2.00	1.81	1.99
ISO 5	2.00	2.00	2.00	2.00	2.00	2.00	2.00	2.00	2.00	2.00	2.00	2.00	2.00	2.00
ISO 7	2.00	2.00	1.80	4.17	2.00	2.00	2.00	2.00	2.00	2.00	2.00	2.00	2.00	2.00
ISO 8	2.00	2.00	2.00	2.00	2.00	2.00	2.00	2.00	2.00	2.00	2.00	2.00	2.00	2.00

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## Key features of the EM Software Solution

- **Digitalization:** unrivaled data collection and trending capabilities for better insights and decisions
- **State of Control:** Continuous real-time data monitoring and result reports in many formats
- **Earlier Contamination Alerts:** Real time trending, early risk assessment and control
- **Alerts:** Key personnel notified and root cause analysis performed upon contamination risk
- **Continuous Improvement:** EM sampling programs assessed to learn from past issues and experiences
- **Traceability:** Full documentation of the process and of all linked or related activities
- **Error Prevention:** Enforced GMP & best practices to minimize critical operator errors
- **Compliance:** Data Integrity, 21 CFR Part 11 & Annex 11, dedicated USP <1116> reporting
- **Business-Ready:** Quick and seamless implementation

# WHAT IT MEANS FOR YOU...

## ... to Advance Customers' Contamination Control to the Next Level to Shape the Future of Contamination Control

The automation and digitalization solution being jointly developed by **Merck** and **Novatek** will go well beyond the partners' proprietary solutions: It will leverage ( optimize ) the Microbial environmental monitoring processes, crucial for the Contamination Control Strategy.

The combination of the two leaders enables pharmaceutical companies to:

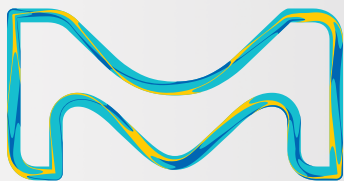
- Optimize Contamination Control Strategy
- Communicate bi-directionally with MAS-100 NT® air samplers to enhance operational efficiency and ease of use (e.g. automated Feller correction) while avoiding data loss
- Automate their environmental monitoring (EM) workflow reducing transcription errors
- Work with a secure 21 CFR Part 11 and data integrity compliant, risk-based EM system
- Chain of custody; Track all culture media via unique barcodes from sampling and incubation, to reading, trending, and reporting of results
- Perform real-time data tracking with automated scheduling to avoid missing samples
- Perform automated, instant trending and reporting of EM data
- Initiate root cause analysis on Alert and Action excursions

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Merck KGaA  
Frankfurter Strasse 250  
64293 Darmstadt, Germany

**[SigmaAldrich.com/environmental-monitoring](https://www.sigmaaldrich.com/environmental-monitoring)**



**The Life Science business of Merck operates as MilliporeSigma in the U.S. and Canada.**

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**NOVATEK**  
**INTERNATIONAL**  
Digitalizing Contamination Control

2537 Guenette Ville Saint-Laurent (Montreal) Quebec, Canada, H4R 2E9  
Webpage : <https://ntint.com>  
Phone: +1 514 668 2835 Fax: +1 514 336 6537  
E-mail: [sales@ntint.com](mailto:sales@ntint.com)