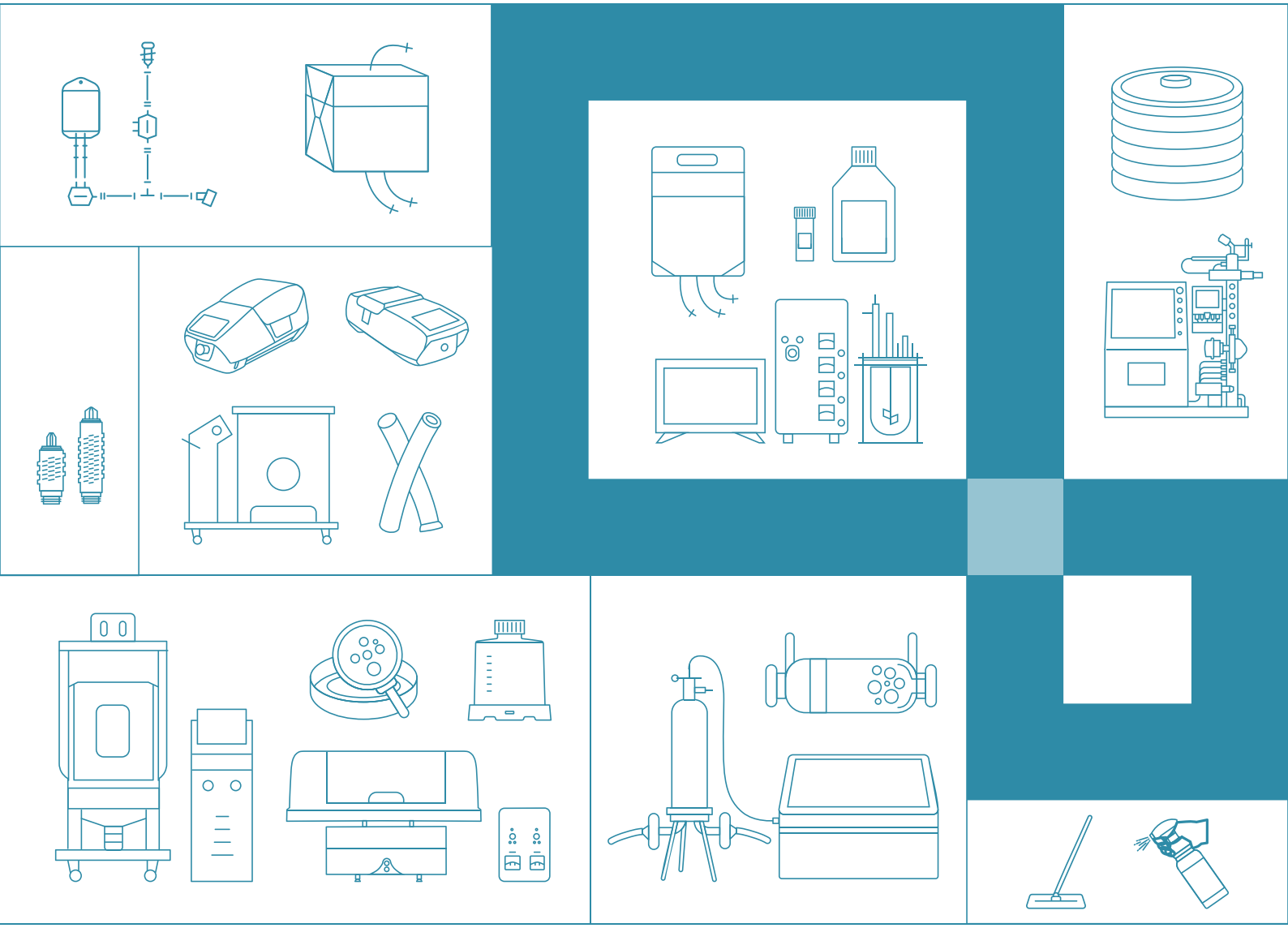
Empowering Pharmaceutical: Products & Solutions Overview

Innovative. Reliable. Scalable.

Empower Biopharma through High Quality Bioprocess Solutions





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About LePure Biotech

LePure Biotech delivers a comprehensive, end-to-end portfolio of single-use bioprocess solutions engineered to empower biopharmaceutical development, scale-up, and commercial GMP manufacturing. Spanning bioprocess bags/films, fluid management components, filtration systems, and process equipment, our offerings are unified by three core strengths that drive bioprocess excellence worldwide:

Drug Discovery



Single-Use Bioprocess



LeKrius® Single-use Bags | Mixing | Storage Equipment | Collapsible Container / Transport Cart | Tubing Assemblies | Plastic pallet / Plastic Drum | Le-Flex® TPE Tubing

Drug Discovery → **Process Development** → **Clinical Trials** → **Process Validation & Commercial Manufacturing**

Filtration Solutions



Microfiltration | Filter Integrity Tester | Hollow Fiber Filtration | Depth Filters and Holder | TFF Cassettes and Holder

Cell Culture Solutions



Culture Media & Cell Lines | Single-use Bioreactor | Rocking Bioreactor | Glass Vessel Bioreactor | Microcarrier Spheres | Cell Carrier Disks | gas-permeable cell culture device | Ready to Use Antifoam

Pharmaceutical Cleanroom Solutions



Cell Culture Solutions

Cell Line Platform

LePure Biotech's mammalian cell line platform provides robust CHO and HEK293 cell substrates to support the development and manufacture of monoclonal antibodies, recombinant proteins, viral vectors, vaccines, and cell & gene therapies.

QuaCell® CHO-K1Q Cell Line

The QuaCell® CHO-K1Q cell line, derived from ECACC and optimized with proprietary engineering, preserves CHO-K1 fundamentals while enabling superior bioproduction performance.

Key Features

- **Performance:** Enhanced productivity while maintaining CHO-K1 lineage characteristics.
- **Yield:** Antibody titers averaging >4 g/L, with peaks up to ~14 g/L.
- **Compliance:** Comprehensive documentation supporting IND and BLA filings, with global Freedom to Operate (FTO).
- **Track Record:** Proven in 300+ projects, including 70+ IND filings.



Cell Culture Media

LePure Biotech offers chemically defined media solutions for CHO and HEK293 cell culture, designed to support robust cell growth, high productivity, and scalable bioprocessing.

Key Features

- **Chemically Defined:** Animal component-free formulations for consistent process performance and regulatory compliance.
- **Optimized Performance:** Supports high-density cell growth, viability, protein expression, and viral vector production.
- **Catalog & Custom Solutions:** Available as standard media products or customized OEM formulations.
- **Regulatory-ready:** Manufactured under GMP and ISO standards with DMF filing available.



WayneLVPro™ HEK293/T Cell Line

Proprietary cell line developed by QuaCell® using advanced high-throughput screening platforms. It features high-density growth, exceptional transient transfection efficiency, and elevated viral expression titers.

Key Features

- **Growth:** High-density suspension growth for scalable manufacturing.
- **Transfection:** Exceptional transient transfection efficiency.
- **Productivity:** Elevated viral expression and vector yields.



Cell Culture Solutions

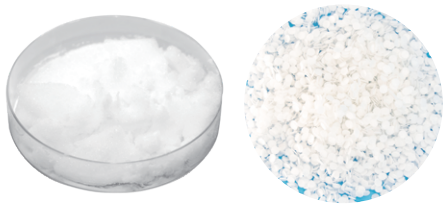
Cell Culture Media

LeProlif® Microcarrier Series

High-performance microcarriers designed for scalable adherent cell culture, supporting robust cell expansion from process development through commercial manufacturing.

Key Features

- **Multiple Formats:** Available in disk and spherical configurations for diverse cell culture needs.
- **High Growth Surface:** Up to 1300 cm^2/g specific surface area for enhanced cell expansion.
- **Process Consistency:** Uniform particle size distribution supports reproducible culture performance.
- **Flexible Sterility Options:** Offered in both gamma-irradiated and non-irradiated formats.



QuaCell® Ready-to-Use Antifoam

Key Features

- **Convenient & Reliable:** Pre-formulated solution with strong defoaming and anti- foaming performance.
- **Simple & Safe:** Single raw material source with no added exogenous components.
- **Flexible Customization:** Bag size, tubing, and connectors configurable to customer requirements.
- **Stable Supply:** Independently manufactured with assured quality and controllable lead times.



Bioreactor and Incubator

LeKrius® Single-Use Bioreactor Bag

Proprietary film technology with a full portfolio for bioproduction from R&D to commercial scale.

Key Features

- **Proprietary Film:** Engineered with LeKrius® film technology for high performance and safety.
- **In-House Manufacturing:** Ensures cost efficiency and reliable supply chain security.
- **Comprehensive Portfolio:** Covers R&D, pilot, and commercial- scale applications.
- **Seamless Integration:** Accessories and components designed for smooth system integration.
- **Flexible Scalability:** 50L to 2000 L culture volumes, enabling both scale-up and scale-down.



Cell Culture Solutions

Bioreactor and Incubator

LeKrius® Rocking Bioreactor Bag



Compatible with the LePhinix® CCS Rocking Bioreactor, LeKrius® rocking bioreactor bags support both suspension and adherent cell culture processes with efficient mixing and gas transfer performance.

Key Features

- **Versatile Cell Culture:** Supports suspension and microcarrier-based adherent cell growth.
- **N-1 Intensification Ready:** Optimized for high-density seed train expansion.
- **Perfusion Capability:** Achieves cell densities up to 100×10^6 cells/mL.
- **Broad Process Utility:** Ideal for cell banking, seed culture, and intensified upstream applications.

LeCulti® Gas-Permeable Cell Culture Device



With high gas permeability, LeCulti® supports healthy cell growth and efficient metabolism, making it ideal for adherent cell cultures.

Key Features

- **Reliable material supply:** Long-term agreements with key suppliers and robust inventory systems secure timely delivery and reduce supply risks.
- **GMP-ready design:** Purpose-built for GMP-compliant cell production, enabling optimized culture conditions, small- scale expansion, and compliance with CGT closure and biosafety standards.

LePhinix® Single-Use Bioreactor



LePhinix® Single-use Bioreactor combines flexibility and scalability to support a wide range of cell culture applications.

Key Features

- **Capacity:** Available from 50 L to 2000 L, with fully customizable configurations.
- **Operation Modes:** Supports batch-fed and perfusion processes for enhanced process flexibility.

Single-Use Solutions

Bioprocess Bags and Equipment

LePhinix® EZG Glass Vessel Bioreactor

The LePhinix® EZG Glass Vessel Bioreactor is a fully compliant and customizable platform engineered for advanced bioprocess development.

Key Features

- **Flexibility:** Open development platform enabling customized, user- specific configurations.
- **Scalability:** Multi-vessel control capability supporting efficient parallel processing and seamless scale-up.



LeKrius® Bioprocess Film

Key Features

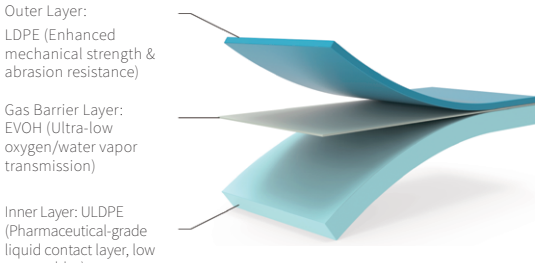
- **Robust Mechanical Durability:** Superior puncture, tear and impact resistance for consistent process integrity.
- **Reliable Process Stability:** Sustains structural and performance consistency across all bioprocessing stages.

Superior Bioprocess Safety

- **Biocompatibility Validated:** Protect cell culture viability and performance.
- **Ultra-Low Extractables & Leachables:** Minimizes process contamination risk and ensures product safety.

Assured Quality & Reliable Supply

- **Proprietary Formulation & Manufacturing:** In-house extrusion technology with fully independent performance validation.
- **End-to-End Quality Control:** Closed-loop, traceable supply chain ensures consistent batch-to-batch performance.



Bioprocess Film

LeKrius® Single-Use Storage & Transfer Solutions

Designed for the safe storage, handling, and transfer of biopharmaceutical fluids, LeKrius® solutions combine validated single-use storage bags with compatible support hardware to enable scalable and secure fluid management across upstream, downstream, and fill-finish operations.

Key Features

- **Versatile Form Factors:** 2D and 3D configurations, 5 mL – 4000 L volume range.
- **Fully Customizable:** Tailored size, tubing, connectors, and integrated filters.
- **Broad System Compatibility:** Seamless integration with all standard bioprocess containers and fluid transfer systems.
- **Complete Support Hardware:** Compatible with trays, drums, IBCs, and mobile transfer carts to enhance handling efficiency and operational safety.



Single-Use Solutions

Bioprocess Bags and Equipment

LeKrius® Single-Use Mixing Bag

Engineered with LeKrius® Bioprocess Film for efficient, sterile liquid-liquid and solid-liquid mixing in bioprocessing.

Key Features

- **Wide Volume Range:** 1 L – 4000 L, with round/square, closed/open configurations.
- **Optimized Mixing Design:** Central or offset mixing options for homogeneous formulation.
- **Configurable Process Monitoring:** Customizable sensor ports for real- time pH/conductivity/temperature tracking.
- **Universal Compatibility:** Fully integrated with all commercial magnetic mixing systems.

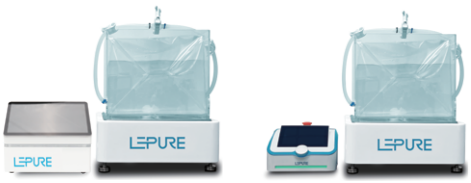


MiniWind Benchtop Mixing System

MiniWind Benchtop Mixing System delivers precise, controlled sterile mixing for 0.5 – 30 L volumes, enabling R&D and small-scale GMP bioprocessing.

Key Features

- **Magnetic Coupling Drive:** Contact-free mixing technology eliminates cross- contamination risk.
- **Integrated Process Control:** All-in-one system with weighing, pH, conductivity and temperature real-time monitoring.
- **Optimized Compatibility:** Custom-engineered for LeKrius® single-use Mixing Bags.
- **Configurable Platforms:** LXB-E (Process Development).



LXB-P LXB-E

LePurweld® Automatic Aseptic Welder & LePurseal® Automatic Aseptic Sealer

Reliable connections across diverse single-use workflows.

Key Features

- **Broad Compatibility:** 1" to 4" OD TPE tubing; dry, wet, or liquid-filled; compatible with major brands.
- **Process Reliability:** Ensures secure, sterile connections for biopharmaceutical production.
- **PVC Solutions:** Specialized welders and sealers available for PVC tubing applications.



Powder Feeding Bags & Systems

Single-use Powder Feeding System for safe, efficient anti-static powder handling in bioprocess media/buffer formulation.

Key Features

- **Anti-Static Performance:** LeDetic® film powder bags enable >99.9% powder recovery efficiency.
- **Modular single-use Assemblies:** 3", 4", 6", 8" bag options with adjustable transfer/ weighing stands.
- **Ergonomic & Safe Design:** Integrated lifting support frame for user-friendly, risk-mitigated operation.



Single-Use Solutions

Filling / Freeze-Thaw / Aliquoting / Storage and Transportion

LeKrius® Freeze-Thaw Solutions

Designed for the safe freezing, storage, transportation, and thawing of biopharmaceutical fluids, LeKrius® Freeze-Thaw Solutions combine proprietary bioprocess film, 3D freeze-thaw bags, and protective enclosures to deliver consistent freeze-thaw performance across development and commercial manufacturing.=



Key Features

- **Uniform Freeze-Thaw Performance:** 3D bag design and optimized enclosure support efficient heat transfer and consistent thawing.
- **Scalable Platform:** Available in flexible 2–12 L formats, with reusable 8 L and 15 L configurations for process-specific applications.
- **Operational Simplicity:** Lightweight integrated support design enables secure handling, transportation, and storage.
- **Validated Reliability:** Verified through long-term freezing, drop, and transportation studies to support critical bioprocess operations.

Aliquoting System

Automated and sterile filling from 1 L to 2500 L, compliant with GMP standards and supported by full validation.

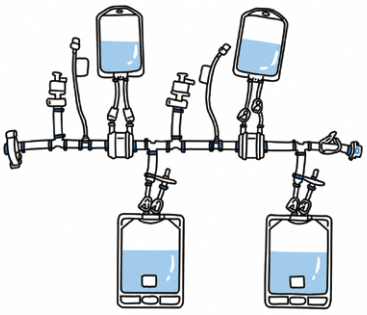


Key Features

- **High Precision:** Intelligent pump system with ± 1 % filling accuracy.
- **Flexible Setup:** Compatible with single-use bags and bottles, modular design for multiple formats.
- **Sterile & Safe:** Sealed single-use fluid path prevents cross-contamination.
- **Traceable:** Integrated data and printing functions ensure process documentation.

Single-Use PUPSIT Assemblies

A configurable single-use solution designed to facilitate pre-use post-sterilization integrity testing (PUPSIT) while maintaining aseptic process security. The assemblies integrate sterilizing-grade filtration, fluid management, and validation support into a streamlined, ready-to-use platform.



Key Features

- **Verified Assembly Integrity:** 100% integrity-tested assemblies ensure reliable performance throughout filtration operations.
- **Enhanced Cleanliness Control:** Optional C+A ultra-clean manufacturing helps reduce particulate and endotoxin introduction risks.
- **Flexible Process Design:** Customizable configurations support a wide range of sterilizing-grade filtration and filling applications.
- **Qualification Support:** Backed by validation documentation, technical consultation, and process implementation expertise.

Filling System



Key Features

- **Ultra-Clean Environment:** Controlled under Class C and A conditions to ensure cleanliness and minimize visible particles.
- **Raw Material Safety:** Pre-rinsing of critical raw materials for reduced contamination risk.
- **Precision Accuracy:** Ultra-tight tubing tolerance control guarantees filling precision.

Single-Use Solutions

Fluid Management Solutions

Le-Flex® TPE Tubing

Designed for closed single-use bioprocessing, Le-Flex® TPE tubing enables sterile welding and sealing while maintaining process flexibility across upstream, downstream, and fill-finish applications.

Key Features

- **Broad System Compatibility:** Weldable with leading thermoplastic tubing platforms, reducing validation burden during process transfer and scale-up.
- **Reliable Aseptic Connectivity:** Consistent welding and sealing performance supports secure fluid transfer throughout upstream and downstream operations.
- **Secure Supply Chain:** Manufactured using proprietary materials and controlled production processes for dependable product availability.
- **Quality & Compliance Support:** Backed by extractables characterization, biocompatibility testing, and complete documentation packages.



Platinum-Cured Silicone Tubing

A versatile tubing platform engineered for fluid transfer, peristaltic pumping, and high-performance bioprocess applications. Available in multiple hardness grades to support a broad range of process requirements.

Key Features

- **Broad Application Range:** Suitable for fluid transfer, peristaltic pumping, pressure-resistant applications, and cryogenic handling.
- **Excellent Mechanical Performance:** High flexibility, kink resistance, and durability support reliable long-term operation.
- **Multiple Performance Grades:** Available in PHA50, PHA60, PHA65, and PHA80 formulations to meet specific process demands.
- **Bioprocess Ready:** Compatible with gamma irradiation and autoclave sterilization, with comprehensive quality and traceability documentation.



Peristaltic Pumps & Tubing

Multi-series pumps supporting flow rates up to 33 L/min, available in mobile and benchtop formats with IP33+ protection.

Key Features

- **Flexible Use:** Adaptable to diverse bioprocessing environments.
- **Pump Tubing:** Class C extrusion, ensuring high cleanliness and ultra-low extractables.



Single-Use Solutions

Fluid Management Solutions

Pharmaceutical-Grade Pressure-Resistant Silicone Tubing & Crimped Tubing

Designed for demanding bioprocess fluid transfer applications, LePure pharmaceutical-grade pressure-resistant silicone tubing combines flexibility, durability, and pressure stability to support upstream, downstream, and fluid management operations.



Key Features

- **High-Pressure Performance:** Reinforced construction provides excellent pressure resistance and dimensional stability for demanding fluid transfer applications.
- **Extended Service Life:** Withstands repeated CIP/SIP exposure while maintaining mechanical integrity and process reliability.
- **Integrated Crimped Assemblies:** Available with customized tubing, connectors, and sanitary fittings to simplify system integration and reduce leak risks.
- **Biopharmaceutical Compliance:** Manufactured from medical-grade silicone materials with comprehensive quality documentation and batch traceability.

LeCouple® KY Sterile Sampling Kit

Single-use Aseptic Sampling Kit engineered for closed bioprocess workflows—no cleaning or sterilization required.





Key Features

- **Closed-System Design:** Eliminates bioprocess contamination and cross-contamination risk.
- **Flexible Sampling:** Enables repeated, representative sampling throughout the process.
- **Global Regulatory Compliance:** Fully aligned with international GMP and bioprocess quality standards.

Single-Use Fluid Components

Standardized fluid path components designed for secure, flexible, and scalable single-use bioprocessing systems.



Key Features

- **Comprehensive Component Portfolio:** Wide selection of sanitary fittings, Tri-Clamp interfaces, adapters, and fluid path accessories for flexible system design.
- **Dual Sterilization Compatibility:** Suitable for both gamma irradiation and autoclave sterilization to support diverse process requirements.
- **Quality & Compliance Support:** Manufactured in controlled cleanroom environments with full batch traceability and supporting quality documentation.
- **Specialized Components:** pH/DO sensor sleeve assemblies designed for closed-system process monitoring.

LeBrider® Tubing Assemblies

Engineered for seamless, end-to-end single-use bioprocess fluid path connectivity, with custom PUPSIT filling system design supported by dedicated technical experts.



Key Features

- **Comprehensive Component Portfolio:** Extensive range of tubing, connectors and fluid handling accessories.
- **Rapid Customization:** Dedicated technical support enables fast configuration and prototyping
- **Uncompromising Reliability:** 100% leak-tested with full test documentation for proven performance.

Filtration Solutions

Filtration

Hydrophilic PES Capsule & Cartridge Filters

UniPore Hydrophilic PES Capsule & Cartridge Filters deliver reliable microbial retention, high flow rates and broad chemical compatibility for a wide range of bioprocessing applications.

Key Features

- **High Flux & Throughput:** Highly asymmetric membrane structure enables superior flow efficiency and process throughput.
- **Pharmaceutical-Grade Purity:** Ultra-pure raw materials and cleanroom manufacturing ensure low extractables.



Hydrophilic PVDF Capsule and Cartridge Filters

The Extreme™ PVDF series delivers high purity, low leachables, and low adsorption-ensuring efficient liquid filtration while minimizing product loss.

Key Features

- **High Purity:** Low leachables with minimal interference.
- **Low Adsorption:** Maximized recovery rate of active ingredients.
- **High Throughput:** Improved filtration efficiency.



Hydrophobic PES Capsule

designed for critical air / gas filtration.

Key Features

- **Sterile Ready:** Pre-sterilized via gamma irradiation; ready-to-use for single-use biomanufacturing lines.
- Pre-sterilized via Gamma irradiation.

Hydrophobic PTFE

LeSiever® Hydrophilic PTFE provides high-efficiency filtration for aggressive and corrosive solutions.

Key Features

- **Strong Hydrophobicity:** Low air resistance ensures high ventilation efficiency.
- **Long Service Life:** Reliable filter integrity; stable in hot air & repeated steaming.



PP

LeSiever® PP is a cost-effective polypropylene depth filter widely used for general pre-filtration across industries.

Key Features

- **High Dirt-Holding Capacity:** Delivers robust throughput and extended service life.
- **Chemically Resistant & Low Extractables:** Broad compatibility; minimal extractable profile; low non-specific binding for higher product yield.



Filtration Solutions

Filtration

LeClafine® Depth Filter Series

High-efficiency clarification with high impurity loading capacity, fast flow rates, and high protein recovery. Scalable from R&D to GMP production.

Key Features

- **High clarification capacity:** High clarification capacity.
- **Dual filtration mechanism:** Mechanical sieving + electro-adsorptive filtration.
- **High-throughput performance:** Fast flow rate with high protein recovery yield.



LeUltra® PES UF Cassettes

LeUltra® PES UF Cassettes feature modified polyethersulfone composite membranes for high flux and long service life, optimized for tangential flow filtration (TFF) in vaccines, antibodies, and biotherapeutics manufacturing.

Key Features

- **Broad Chemical Compatibility:** Delivers high flux & high product recovery.
- **Two Flow Channel Options:** Adaptable to diverse process conditions.
- **Excellent Linear Scalability:** Fixed channel length & stable height ensure robust scale-up.
- **Easy to Clean & Reusable:** Long service life; lower cost of ownership.



Supporting Products



UF Clamp

LeFiber® Hollow Fiber TFF Module

High-performance hollow fiber membrane modules for concentration, diafiltration, cell harvest, and purification applications.

Key Features

- **Low Protein Adsorption:** Modified mPES membrane supports high product recovery.
- **High Flux & Separation Efficiency:** Narrow pore size distribution enables efficient processing and reduced cycle times.
- **Enhanced Fouling Resistance:** Hydrophilic membrane surface promotes stable long-term performance.



LeSiever® LFT-1010 Integrity Tester

High-performance automated filter integrity testing, fully compliant with GMP bioprocessing.

Key Features

- **Comprehensive Test Methods:** Automated bubble point, diffusion flow, pressure hold, water intrusion.
- **Real-Time Monitoring:** Live test data and curve visualization for full visibility.
- **Precision Control:** Microelectronic airflow regulation for consistent testing.
- **High Efficiency:** Optimized algorithms reduce cycle time by 20–30 %.
- **Data Integrity:** Scientific data management with full audit trail for compliance.

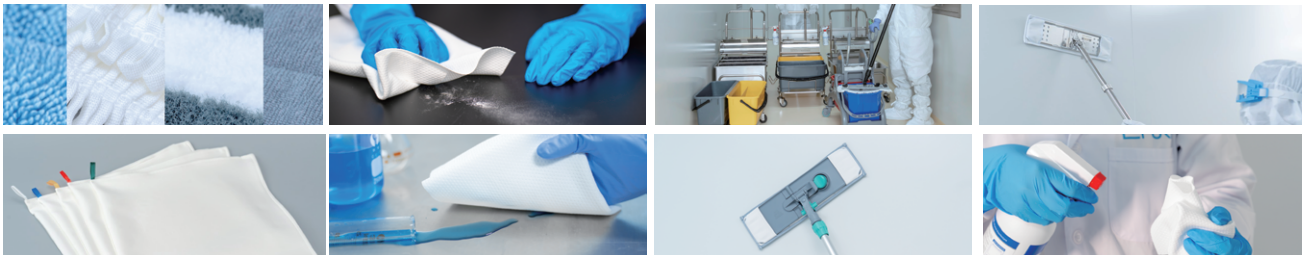


Pharmaceutical Cleanroom Solutions

Cleanroom Cleaning Product Series

- **Dust-Free Wipe Series**: High-efficiency particulate and microbial removal
- **Mop Series:** Optimized for GMP-grade aseptic cleaning
- **Wipe Series:** Durable, low-lint materials for sensitive environments
- **Cleaning Trolley Series:** Ergonomic, compliant with cleanroom workflow

All products meet GMP Grade A/B/C/D cleanroom standards and are supported by comprehensive documentation, including durability reports, sterilization validation, technical data sheets, wiping efficiency data, material specifications, and Certificates of Analysis (COA).



Cleanroom Industry Personal Protection Equipmeat

Full-spectrum personal protection solutions for cleanroom Grades A–D, including single-use and reusable garments, accessories, and integrated systems. Each product is engineered to control personnel-driven contamination and maintain compliance with GMP requirements.

- Cleanroom gowning
- Cleanroom gloves
- Shoe covers
- Cleanroom masks
- Autoclavable goggles





★ Sales Territory and Display Disclaimer

Most of the products shown in this brochure are available in China and international markets.

Some products, such as those displayed across two pages, are only available in China and certain Southeast Asian markets.

In other regions, they are displayed solely to illustrate our portfolio and technological capabilities.

Disinfectant and Sporicides

We provides a comprehensive range of disinfectants, including:

- **Ready-to-use:** alcohol-based, quaternary ammonium compounds, 3 % hydrogen peroxide, 6 % hydrogen peroxide, and compound peroxide formulations
- **Concentrates:** compound peroxide (Type II) and compound quaternary ammonium (Type II)

All products are supported with complete technical documentation, including COA, MSDS, microbial efficacy validation, irradiation validation, and safety evaluations.



advanced sterile solutions
A LePure Biotech Company

LePurValid® Validation Services

Safeguard Process Safety, Compliance, and Speed-to-Market

We understand the critical compliance and verification pressures in biopharmaceutical development and manufacturing. Backed by international standards and dual-certified platforms, LePurValid® Validation Services support efficient qualification of single-use systems, filters, and core consumables. We reduce compliance risk, accelerate time-to-market, and help ensure drug safety with cost-effective, robust validation solutions. risks, shortening time- to-market, and safeguarding drug safety with greater cost efficiency.



A

Core Consumable Validation

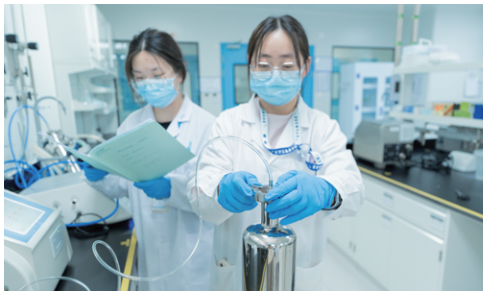
- Single-Use Systems (SUS)
- Filter Products (Filters, Depth Filters)
- Disinfectants

We offer a full range of services including SUS compatibility studies, filter validation, and disinfectant efficacy testing.

B

Extended Requirement Validation

- Evaluative Documentation Support
- Pharmaceutical Packaging Compatibility
- Consumable Stability in Medical Devices
- Consumable-to-Consumable Compatibility
- Water Quality Analysis
- Helium Leak Testing



Global Footprint

All our products meet global bioprocess quality standards, with CE certification and comprehensive regulatory documentation to support global market deployment.



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