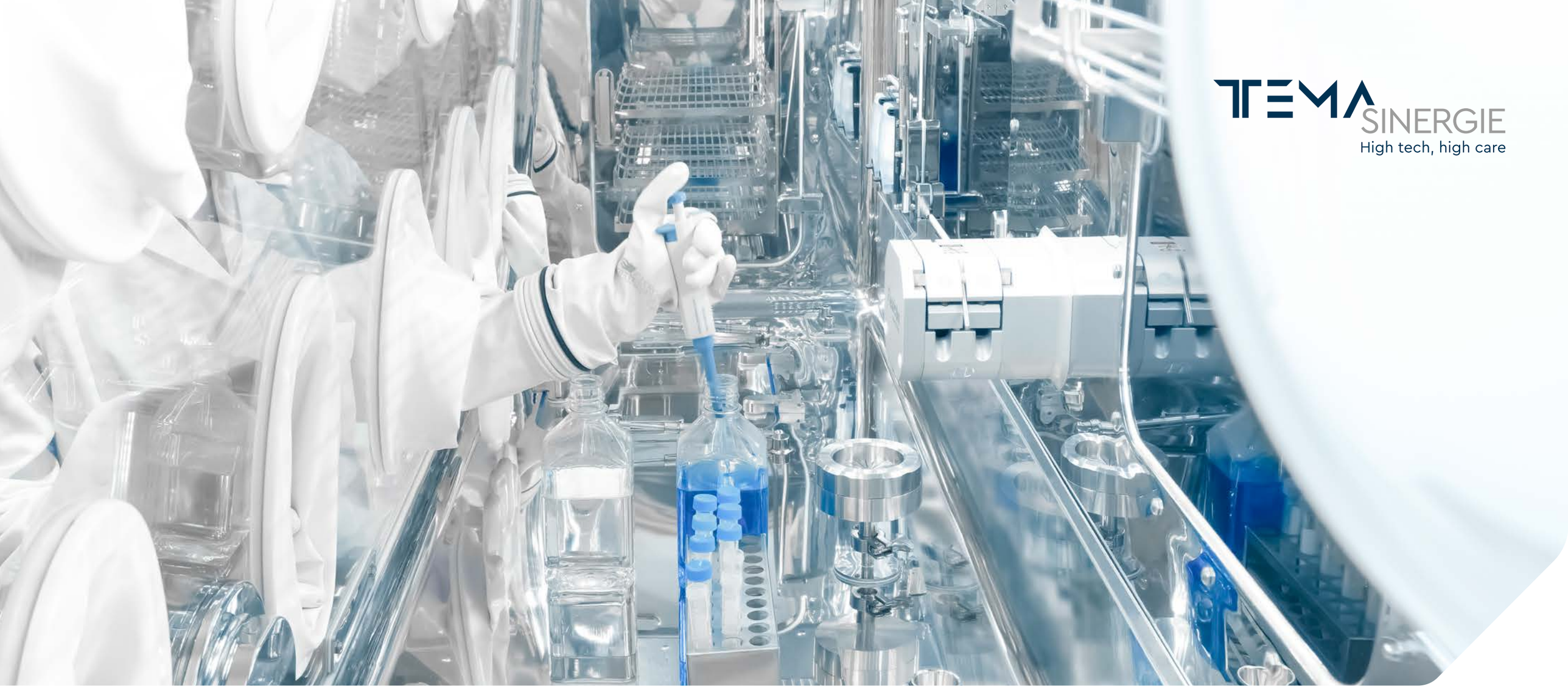

TEMA SINERGIE
High tech, high care

Pharma & ATMP

Integrated Turn-key solutions for containment and aseptic processes

The One-Stop Shop for your pharmaceutical process

We are probably the best answer to your needs

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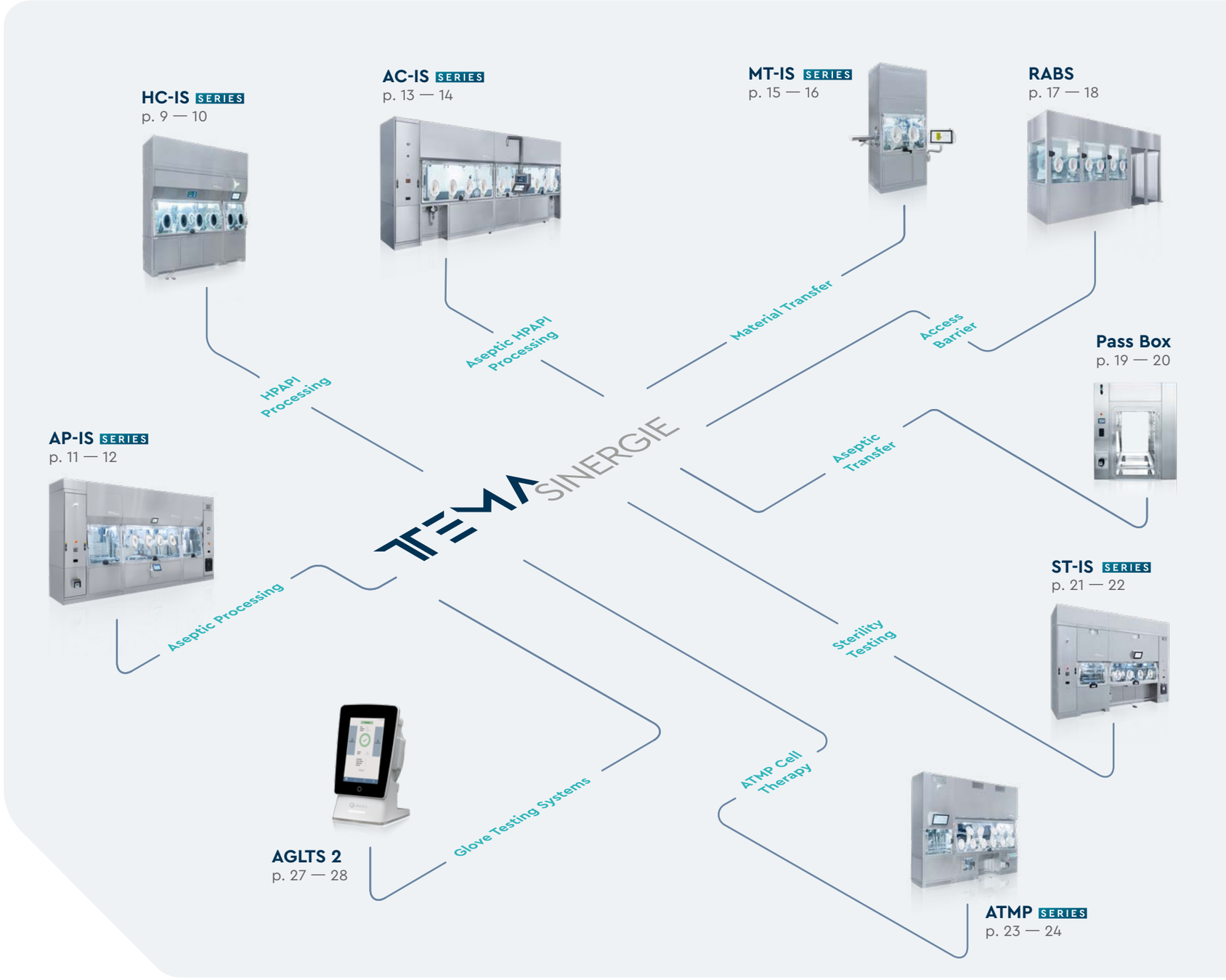


Welcome to Tema Sinergie

Our journey began in Faenza, Italy, in 1985.
Today we have customers in more than 90 countries around the world, and we continue to conceive, design and deliver solutions with the same enthusiasm and spirit as when we first started.

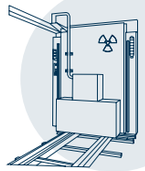
A great journey

1985

Tema Sinergie was founded. The company provides shielded accessories and manipulation tools for nuclear power plants. Due to the Chernobyl disaster in 1986, the Italian market is put at risk. As a consequence, the focus of the Compnay shifts to the medical sector.

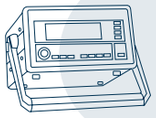
1990

Starting by meeting the needs of research institutes and the first Nuclear Medicine Departments operating in Italy, Tema Sinergie begins to design, manufacture and install radioactive organic waste management systems, shielded doors, radiation monitoring systems and calibration irradiators.



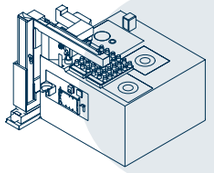
1993

As being involved in the Radiotherapy field with the production of shielded doors and radiation monitor systems, Tema Sinergie acquires the distribution in Italy of international brands manufacturing Radiotherapy related products. A new business is born, that of Resale of equipment for Radiotherapy and Medical Physics Departments.



2005

The global development of PET (Positron Emission Tomography) is opening new doors, and Tema Sinergie enters this market by launching its first automatic dispenser. The Company is committed to innovation and process automation.



1985
FOUNDATION

20.500 SQM
PRODUCTION PLANT

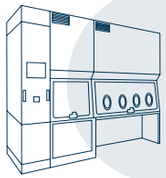
280
EMPLOYEES

2.400+
CUSTOMERS

90+
COUNTRIES WITH INSTALLATION

2012

Tema Sinergie is recognized as a global leader in shielded isolator manufacturing. The company decides to expand its product portfolio by designing and manufacturing barrier systems, isolators and integrated solutions for the Pharma & Biotech sectors.



2022

The Company is quickly growing up; the introduction of Theranostics is significantly expanding the target market. A new business partner, Charme Capital Partners private equity fund, has joined Tema Sinergie, holding 70% of the shares.

Charme Capital Partners

2023

The Company establishs its very first branch office in the USA. The office is focused on after-sales service, enabling our technicians to operate more efficiently within the North American territory.

2024

As the Company's expansion continues to accelerate, the facility in Faenza triples in size, reaching 20,500 m². With nearly 300 employees, we continue to look towards the future...

Promoting a Better Quality of Life

Our know-how at the service of health, well-being and safety

Professionalism, proactivity, passion and business intelligence are features that distinguish us every day since 1985. These qualities allow us to become a reliable partner. We are a multidisciplinary, dynamic and innovative group of people, focusing on our mission: promoting a better quality of life.

We closely collaborate with our customers, providing our expertise to deliver the most suitable solutions to meet their specific needs. Our wide range of services aims to improve the quality and safety of the operators.

We are organized in multidisciplinary dedicated teams that work closely together on a daily basis. Continuous sharing of internal knowledge allows our business units to enhance their know-how.

We collaborate with leading companies in the Pharma, Biotech, Nuclear Medicine and Radiotherapy sectors, offering dedicated solutions that meet international standards.

Pharma & ATMP

Integrated solutions for the pharmaceutical industry of tomorrow

Tema Sinergie is a technological benchmark for the production of customized barrier systems designed for the global pharmaceutical market. We specialize in the design and manufacture of aseptic isolation and containment technologies to address the requirements of pharmaceutical and biotech companies, as well as industrial partners implementing large automated production lines.

ATMP, cell culture manipulation, aseptic processes, HPAPI handling, sterility testing, product transfer in controlled environments, and glove integrity testing on isolators and RABS are just a few of the applications we have offered to the global market over the years.

Our technological leadership in the field of isolation technology is based on a combination of multiple factors. It began with a pioneering experience in the design and production of shielded isolators for the handling of injectable radiopharmaceuticals. Over the years, we have developed a highly specialized expertise in developing solutions for the pharmaceutical market, ensuring compliance with the most strict industry regulations.

People are our true added value. We rely on a multidisciplinary team of highly experienced designers, sales engineers, project managers, product specialists, quality control specilists, technicians and engineers. Our expertise makes us your ideal partner to take care your whole project, from:

- Process engineering
- Concept design
- Detail design
- Project management
- Production
- Installation
- Validation
- Training
- Maintenance

The cutting edge technology that meets your needs

Solutions to optimize operator safety and operational efficiency

Tema Sinergie develops solutions with a strong focus on the specific process, prioritizing user comfort for daily operations. Since the very initial pre-sales stages, our technical sales team closely collaborates with the customer, providing dedicated engineering consultancy and defining the broad specifications of the application.

Isolator design is constantly being enhanced, thanks to ongoing dialogue with our customers.
Continuous and calculated research of high quality materials and components guarantees our solutions a high level of quality and safety. Our barrier systems are designed for global installation, manufactured in strict accordance with regulations set forth by the U.S. Food and Drug Administration (FDA) and equivalent bodies in Europe, the Middle East, and Africa (EMEA). Moreover, we prioritize environmental protection as defined by the Control of Substances Hazardous to Health (COSHH) and the Occupational Safety and Health Act (OSHA).

+ Equipment Integration

We strive to integrate our products with the equipment and accessories required for specific processes. We manage integration activity directly with third-party companies, guaranteeing a final result of the highest quality standard.

+ Ergonomic Design

All Tema Sinergie isolators are conceived and designed to be operator-friendly, in accordance with the international principles of human ergonomics. Customer needs are a key part of our design process.
Our primary goal is to enhance user operability to minimize the risk of accidents and eliminate downtime.

+ From idea to prototype

We develop full-scale mock-ups to test required ergonomic and customizations, optimizing the design process and preventing time-consuming adjustments during production.

High Tech, High Care Solution

When it comes to technology, we prioritize safety, sustainability and effectiveness

Competences for the industry of the future

Expert and continuous software development ensures very high levels of security and privacy across all our equipment, contributing to the constant improvement of working processes, facilitating data acquisition and storage, generating customizable reporting, managing alarms and tracking all performed operations.

Our technicians have a in-depth knowledge in automation, along with an extensive experience in system integration and plant-wide networking.

+ Integration

Integration is a key point in the development of our isolators, which consists of mechanical, electrical and automation integration. This includes integration not only among different equipment of our own manufacture, but also with those from carefully selected third-party suppliers.

+ Security

All of our systems comply with 21 CFR Part 11 regulations. We ensure the complete data protection and privacy, in full compliance with GDPR regulations. The software is designed to monitor user access, date/time synchronization, reporting, and electronic (validated) execution of all operations. Diagnostics, reports and trends data are always available, historicizable and capturable in real time.

+ Energy Saving:

Our qualified engineers design isolator systems in order to minimize environmental impact. All systems are compliant with ErP regulations, boasting high efficiency and energy conservation. Targeted design choices, high-efficiency components, modular design, and optimization of control dynamics make Tema Sinergie isolators not only reliable, durable, and secure but also able to operate with minimal energy consumption even when fully operational.

HC-IS SERIES

High Containment Isolator Systems

CLICK HERE OR SCAN THE QR CODE TO LEARN MORE

HC-IS SERIES

Designed for the pharmaceutical industry that demand the highest containment levels for a safe handling of High Potent Active Pharmaceutical Ingredients (HPAPIs).

CLICK HERE OR SCAN THE QR CODE TO LEARN MORE

Tema Sinergie HC-IS Series is a complete range of High Containment Isolator Systems designed to maximize the operator protection during manipulations of High Potent Active Pharmaceutical Ingredients during pharmaceutical primary production. These systems are specifically manufactured for pharmaceutical companies that require the highest containment levels during R&D, production and QC operations. Thanks to a perfect combination of design and manufacturing strategies, HC-IS Series assures incredibily stringent Operator Exposure Levels (OEL≤20 ng /m3).

Applications

Typical applications: Product Transfer, Manual Sampling, Weighing and Dispensing operations of Highly Potent Active Pharmaceutical Ingredients (HPAPIs).

Compliances

OEL ≤20 ng /m3, cGMP Class 2 according to ISO 14644, FDA CFR 21 part 11, GAMP 5, ATEX, Containment Test according to SMEPAC.

+ Pharmaceutical primary production

Containment Isolators are available in standard configuration, or can be customized to cover a wide range of processes, from HPAPIs synthesis to the final formulation. Customized solutions for chemical synthesis and manufacturing processes are designed in accordance with user requirements, including Multi-stages Containment Isolator Systems that guarantee the lowest Operator Exposure Levels (OEL).

+ Equipment integration

We have the technical capability which allows the integration of process equipment, for example Vacuum Dryers, Reactors, Weighing Scales, and High Containment Split Butterfly Valves (HCSBv), makes HC-IS Series the perfect solution for all containment requirements.

AP-IS SERIES

Aseptic Processing Isolator Systems

CLICK HERE OR SCAN THE QR CODE TO LEARN MORE

AP-IS SERIES

Designed for pharmaceutical and biotechnology industries.

CLICK HERE OR SCAN THE QR CODE TO LEARN MORE

Tema Sinergie AP-IS Series provides a comprehensive range of totally aseptic isolators, fully compliant with the strictest cGMP and international regulations.
The high level of aseptic conditions achievable (cGMP Class A/ISO 5) makes these isolators the perfect solution for pharmaceutical and biotechnology industries.
Modular based configurations or custom design to fit specific user requirements.

Applications

Typical applications: R&D, Small Batch Scale Aseptic Filling, Aseptic Dispensing & Sampling of APIs, Aseptic Transfer.

Compliances

Annex 1, EU Guidelines, cGMP, GAMP 5, FDA CFR 21 Part 11.

+ Decontamination Process

The bio-decontamination process is performed by HYPER, Tema Sinergie's Integrated Vapour Phase Hydrogen Peroxide (VPHP) Generator for fast decon cycles.

+ AseptiFill

Tema Sinergie develops custom-designed barrier systems with fully integrated with fill and finish equipment. The machines may be configured and used in both R&D laboratories and small batch scale production suites for ophthalmic, injectable and oral preparations.

AC-IS SERIES

Hybrid Aseptic Containment Isolator System

CLICK HERE OR SCAN THE QR CODE TO LEARN MORE

AC-IS SERIES

For aseptic processing of HPAPIs. Designed for pharmaceutical industrie.

CLICK HERE OR SCAN THE QR CODE TO LEARN MORE

Tema Sinergie AC-IS Series is a complete range of Aseptic Containment Isolator Systems designed for sterile processing of High Potent Active Pharmaceutical Ingredients (HPAPIs), including cytotoxics. The systems can be configured for R&D laboratories and production suites.

Aseptic Containment Isolators are specifically engineered to ensure the highest level of asepsis and to maximize operator protection, in compliance with the strictest cGMP and international regulations. By combining the experience gained through years in design and production of aseptic and containment systems, AC-IS Series can grant a cGMP Class A/ISO 5 environment and an OEL≤20 ng / m3 level operator protection. Cost-effective upgradable standard systems are available, as well as process specific, fully customized solutions.

Applications

Typical applications: Synthesis & Final Formulation, Aseptic Product Transfer, Manual Sampling, Weighing and Dispensing operations of Highly Potent Active Pharmaceutical Ingredients (HPAPIs).

Compliances

Annex 1, EU Guidelines, cGMP, OEL5 (≤50 ng / m3), GMP Class 2, Containment Test according to SMEPAC, Gamp5, FDA CFR 21 part 11.

+ Decontamination Process

The bio-decontamination process is performed by HYPER, Tema Sinergie's Integrated Vapour Phase Hydrogen Peroxide (VPHP) Generator for fast decon cycles.

MT-IS SERIES

Isolators for material bio-decontamination and aseptic transfer processes.

CLICK HERE OR SCAN THE QR CODE TO LEARN MORE

MT-IS SERIES

Designed for pharmaceutical and biotechnology industries.

CLICK HERE OR SCAN THE QR CODE TO LEARN MORE

Tema Sinergie MT-IS Series is a range of aseptic isolators, fully compliant with the strictest cGMP and international regulations, optimized for material bio-decontamination and aseptic transfer.

The large hatch with the integrated VPHP technology allows a safe and fastest biodecon transfer porcess. The stainless steel design is suitable for different cleanroom classifications.

Standard configurations available.

Applications

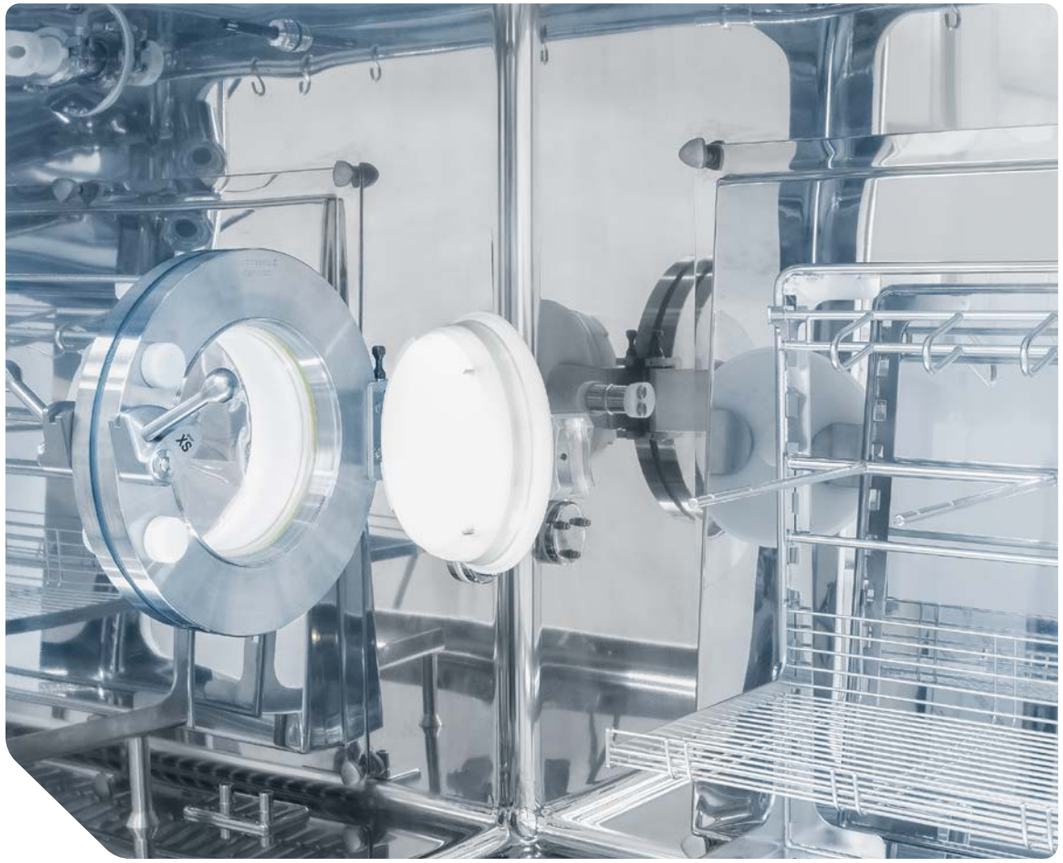
Typical applications: material bio-decontamination and aseptic transfer.

Compliances

Annex 1, EU Guidelines, cGMP, GAMP 5, FDA CFR 21 Part 11.

+ Decontamination Process

The bio-decontamination process is performed by HYPER, Tema Sinergie's Integrated Vapour Phase Hydrogen Peroxide (VPHP) Generator for fast decon cycles.



RABS

Restricted Access Barrier Systems for aseptic processes

CLICK HERE OR SCAN THE QR CODE TO LEARN MORE

RABS

Designed for pharmaceutical classified cleanrooms.

CLICK HERE OR SCAN THE QR CODE TO LEARN MORE

Tema Sinergie RABS Series is developed to meet all applicable requirements for aseptic processing. From small to large batch production systems, our proficiency extends to all fields that require particular attention to asepsis during filling processes for both non-toxic sterile and cytotoxic products, which require totally enclosed environments. Tema Sinergie offers different kinds of custom-designed barrier systems by directly managing the integration activities with a party machine manufacturer and the end user.

Open Passive RABS: barrier system which utilizes existing cleanroom overhead air supply systems to deliver HEPA filtered air over a critical process before returning air back into the clean room.

Open Active RABS: barrier system which has an integrated ventilation system to supply HEPA filtered air over a critical process before returning air back into the clean room.

Closed RABS: a positive pressure system which has an integrated ventilation systemto supply HEPA filtered air over a critical process, which can pass through return filters before being recirculated. Closed RABS can also be integrated with Bio-decontamination system to provide with a cGMP class A/ISO 5 environment.

Specific equipment can be also supplied along with the barrier system, such as for example Preparation Isolator Systems, Unidirectional Airflow Carts, Active Bio-decon Pass Through Chambers, Sterility Testing Isolators to perform all the process steps.

Applications

Typical application: Filling processes

Compliances

Annex 1, EU Guidelines, cGMP, GAMP 5, FDA CFR 21 Part 11.

+ Decontamination Process

The bio-decontamination process is performed by HYPER, Tema Sinergie's Integrated Vapour Phase Hydrogen Peroxide (VPHP) Generator for fast decon cycles.

AB-PTC SERIES

Active Biodecon Pass Through Chamber

CLICK HERE OR SCAN THE QR CODE TO LEARN MORE

AB-PTC SERIES

For material bio-decontamination and aseptic transfer processes. Designed for pharmaceutical laboratories.

CLICK HERE OR SCAN THE QR CODE TO LEARN MORE

Tema Sinergie AB-PTC Series is a comprehensive range of Active Biodecon Pass Through Chambers (cGMP Class A/ISO 5) designed for pharmaceutical companies whom require an isolated environment for external bio-decontamination of materials prior to their transfer into classified environments.

These chambers are the optimal solution for multiple applications, such as aseptic transfer of materials from a lower classification area (Class C) to another of a higher classification (Class B or cleanroom), or decontamination of equipment from BSL-1 through 4 organisms prior to extraction from the facility.

Custom-designed to fit specific user requirements. Walk-In configurations available.

Applications

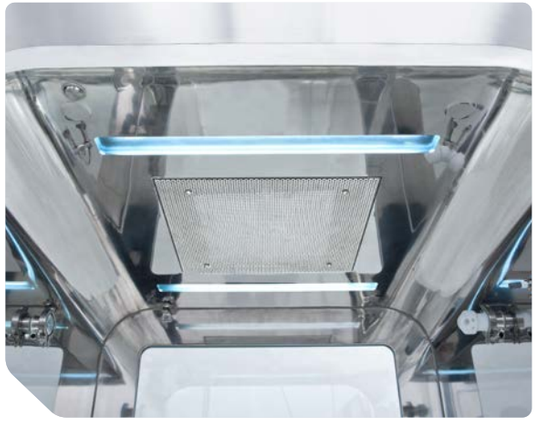
Typical applications: material bio-decontamination and aseptic transfer, transfer, decontamination.

Compliances

Annex 1, EU Guidelines, cGMP, GAMP 5, FDA CFR 21 Part 11.

Decontamination Process

The bio-decontamination process is performed by HYPER, Tema Sinergie's Integrated Vapour Phase Hydrogen Peroxide (VPHP) Generator for fast decon cycles.



ST-IS SERIES

Sterility Testing Isolator System

CLICK HERE OR SCAN THE QR CODE TO LEARN MORE

ST-IS SERIES

Designed for pharmaceutical quality control and microbiology laboratories.

CLICK HERE OR SCAN THE QR CODE TO LEARN MORE

Tema Sinergie ST-IS Series provides a comprehensive range of aseptic isolators, fully compliant with the strictest cGMP and international regulations, specifically designed for Sterility Testing. The high level of aseptic conditions achievable (cGMP Class A/ISO 5) and the integrated sterility testing pump guarantees the safest working conditions during quality control operations.

Modular based configurations or custom-designed to fit specific user requirements.

A compact configuration (CST-IS) is available.

Applications

Typical applications: Sterility Testing, Quality Control operations.

Compliances

Annex 1, EU Guidelines, cGMP, GAMP 5, FDA CFR 21 Part 11.

+ Decontamination Process

The bio-decontamination process is performed by HYPER, Tema Sinergie's Integrated Vapour Phase Hydrogen Peroxide (VPHP) Generator for fast decon cycles.

+ Sterility testing pump

The integrated Sterility Testing Pump is optimized for extremely convenient sterility testing inside isolators. Its table-integrated design offers an easier cleanability, more working space and loading volume in the isolators.

Compact version · **CST-IS**

ATMP SERIES

Cell and Gene Therapy
Regenerative Medicine solutions

CLICK HERE OR SCAN THE QR CODE TO LEARN MORE

ATMP SERIES

For tissue-engineered processes. Designed for R&D and cell factories.

CLICK HERE OR SCAN THE QR CODE TO LEARN MORE

Tema Sinergie ATMP Series is a comprehensive range of cGMP compliant isolators dedicated to production and manipulation of Advanced Therapy Medical Products for medical treatments and research purposes.

cGMP Class A/ISO 5 isolator systems specifically designed to provide the users with an environment which is safer than traditional biosafety cabinets and standard cleanrooms, by eliminating any risk from contamination of cell cultures.

ATMP Series are equipped with Unidirectional Air Flow, and Integrated biodecontamination system to allow 6-log bacterial reduction. Full integration of specific process equipment, for example incubators, digital microscope, and centrifuge.

Applications

Typical applications: autologous therapy activitiy processes, activation and transduction process of non-infectious viruses, viral vectors, allogeneic therapy activity processes, Gene Therapy processes.

Compliances

Annex 1, EU Guidelines, cGMP, GAMP 5, FDA CFR 21 Part 11.

+ Decontamination Process

The bio-decontamination process is performed by HYPER, Tema Sinergie's Integrated Vapour Phase Hydrogen Peroxide (VPHP) Generator for fast decon cycles.

HYPER

Vapour Phase Hydrogen Peroxide (VPHP) Generator

CLICK HERE OR SCAN THE QR CODE TO LEARN MORE

HYPER

For bio-decontamination processes.
Designed for pharmaceutical and biological applications.

CLICK HERE OR SCAN THE QR CODE TO LEARN MORE

HYPER is intended for use in the pharmaceutical and radio-pharmaceutical industries, with the purpose of guaranteeing aseptic processes, for example aseptic transfer of materials and tools, handling and production of drugs, and performance of sterility testing.

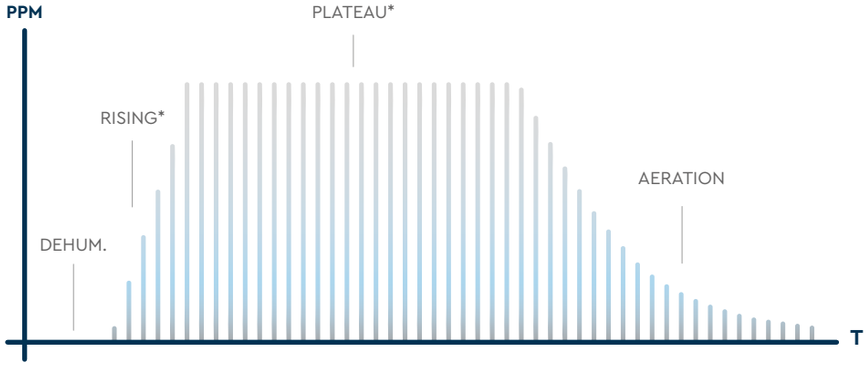
Processes are validated using biological indicators Geobacillus stearothermophilus to consistently achieve a 6-log sporicidal reduction. HYPER works in single pass (open loop) configuration to achieve fast biodecontamination cycles. It is controlled by a Siemens PLC S7 Series to ensure a safe control process and generate a complete bio-decontamination cycle report. HYPER can be either integrated within the isolator structure or externally located. To eliminate operators' exposure to the liquid hydrogen peroxide during handling of bulk product, HYPER uses specifically designed disposable containers of 35% Hydrogen Peroxide (H2O2).

Applications

Typical applications: Aseptic Productions, Sterility Testing, Quality Control operations.

Compliances

Annex 1, EU Guidelines, cGMP, GAMP 5, FDA CFR 21 part 11.



*The time is affected by injection rate, airflow rate, enclosure volume, enclosure contents and temperature.

AGLTS 2

Beyond Glove Testing

CLICK HERE OR SCAN THE QR CODE TO LEARN MORE

AGLTS 2

Designed to perform glove integrity testing according to the positive pressure decay method.

CLICK HERE OR SCAN THE QR CODE TO LEARN MORE

AGLTS 2 is the latest fully automatic cGMP compliant glove integrity testing system for isolators and RABS in the pharmaceutical industry, developed referring to the Positive Pressure Decay Method which follows the international standard ISO 14644-7 Annex E.5.

A new generation device way beyond the simple execution of glove testing, supporting operators and pharmaceutical customers in the management of glove testing related operations.

Applications

Typical application: glove integrity testing in barrier systems, such as isolators and RABS.

Compliances

Annex 1, EU Guidelines, GMP, ISO 14644-7 Annex E.5, GAMP 5, FDA CFR 21 Part 11.

+ Glove Life Cycle Management

It is a significant innovation introduced by AGLTS2, especially highlighting EU cGMP ANNEX 1. This unprecedented feature provides the operator with a clear and immediate view of all the data related to the gloves, both tested and wating to be tested, and of the entire life cycle of the glove itself.

+ iAGLTS Remote Supervision System

iFIX based Remote Supervisor for Automatic Glove Leak Testing System – for data archiving, data management, and report consultation.

Human Machine Interface

Simple human-machine interaction

Intuitive operation: a single touch does it all.

As an international standard, tipically isolators are equipped with Siemens S7 Series PLC and SIMATIC HMI IPC277E Nanopanel, featuring a user-friendly touch panel with a widescreen TFT color display. The operator interface developed by Tema Sinergie allows straightforward and intuitive use. The management software complies with GAMP5 and FDA 21 CFR Part 11.

The "one-touch" function simplifies operations for the user. Stored working programs can be easily retrieved by the user.

Gamp 5 — Good Automated Manufacturing Practice

FDA — Electronic records and Electronic signatures

+ Touch panel

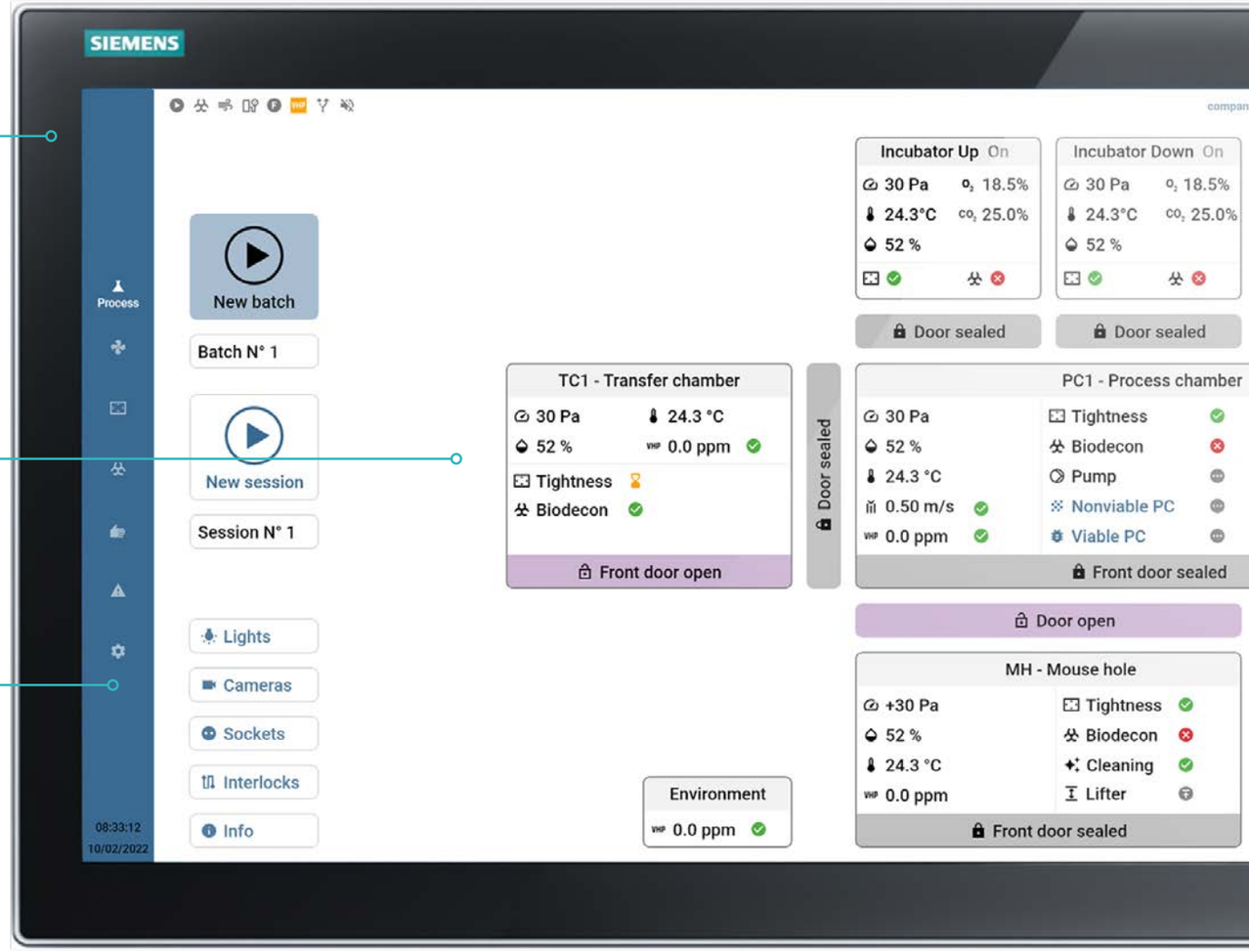
The comprehensive human-machine interface reliably records all relevant data of ongoing process.

+ User friendly

Intuitive graphical interface designed to facilitate the operator.

+ Data management

Flexibility in data management and storage that can be accessed directly or shared quickly and easily within the client's network.



We help you make your Tema Sinergie equipment last longer

Improve the performance of your barrier system

Tema Sinergie provides constant technical support to ensure that your equipment operates at the highest level of reliability and production capacity. Customers can rely on technicians with extensive industry experience, and factory trained to deliver prompt remote service, on-site intervention, and quick supply of original spare parts.

Tema Sinergie can provide customized maintenance contracts to ensure an effective and efficient service support.

Documentations & Validation

- General layout, P&ID, Electrical Diagrams, Pneumatic Diagram
- DS, FS, HDS, SDS
- Certifications of the materials & datasheets of the commercial components
- User Manual, Maintenance & Service Documentation
- Factory Acceptance Test (FAT), and Site Acceptance Test (SAT)
- Installation Qualification/Operational Qualification (IQ/OQ) protocol and execution
- Biodecon Cycle Development (CD) protocol and execution
- Performance Qualification (PQ) protocol and execution upon request

- **Remote Support:**

  Our company also excels in providing continuous and effective remote support. Our technicians analyze various issues, conduct diagnostics, perform software and parameter backups, overhaul machine settings, and carry out specific recalibrations, assisting you until the application is fully restored. Equipment connectivity and support are accomplished in real-time through a secure VPN connection. This proactive apporach minimizes isolator downtime. Our Help Desk service additionally provides end-users with technical support, ensuring a 24/7 service through a dedicated agreement.

All over the world

A worldwide network at your service

Italian innovation and excellence – international presence

Striving to improve the quality of life through advanced solutions and the expansion of perspectives is what characterizes those who, like us, embrace a global approach. Thanks to an established network of carefully selected partners, we operate in more than 90 countries, offering our "Designed and manufactured in Italy" technology to more than 2,000 customers worldwide.

Tema Sinergie carefully chooses its partners, ensuring consistent quality and dedication.Reliability, experience, open dialogue, and continuous improvement are just some of the fundamental attributes that define our partnerships.

Our local presence extends beyond the commercial aspect, providing technical support and assistance thanks to the specialized training of our partners.

Tema Sinergie in USA:

In response to the growing demand in the United States and the increasing need for a local physical presence, Tema Sinergie made a strategic investment in 2023 by establishing its very first branch office, located in New Jersey. The primary focus is to provide our end users with specialized local after-sales services.

BRANCH

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TEMA SINERGIE

High tech, high care

TEMASINERGIE.COM