ISOCARE

Sterility Testing
Isolator

iwt®

ISOCC

SMARTCARE:
Process Augmented Reality

▶ Unlock the full potential of your employees with Augment Reality applied to your process. Improve quality and productivity feeding your operators with projected in-line process information, Track & Trace every step you want, minimizing risks. Use the power of the SMARTCARE platform to supervise, support and educate.

LIGHTCARE:
Dynamic Lighting System

▶ The intelligent lighting system is designed to influence operators' well-being and performance. Light can be adjusted to individual circadian rhythm, reducing fatigue and optimizing operational efficiency. Personalize light adapted on processes and operators' specific needs.
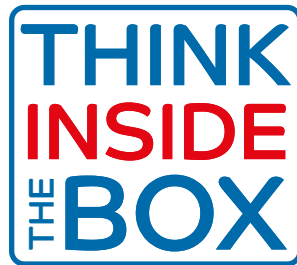
Elevate Quality, Care for Safety.

ISOCARE is the most innovative and robust system c asetpic environment, according to EU-GMP (ISO 5), fo Crafted with Italian manufacturing excellence, it ensu and operators in aseptic and aseptic-toxic operations

MORE COMPACT

Isolator (mm)	3400 x 1150 x 2500
Working Chamber (mm)	1900 x 750 x 800
Transfer Airlock (mm)	700 x 600 x 800

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onceived and designed to provide a clean and
or the manipulation and protection of sterile products.
res the highest level of protection for both products
s.

ISOCARE

iwt

MORE EFFICIENT

▶ The built-in Decontamination System by IWT automatically executes safe and rapid cycles optimizing your process with less worries

▶ The integrated H_2O_2 catalyzer allows to safely exhaust air into the surrounding environment

▶ Your choice of Sterility Testing Pump (*Merck Millipore Symbio or Sartorius Sterisart*) is safely installed into the isolator

▶ Your choice of Environmental Monitoring System is accurately integrated into the isolator

▶ Integrated H_2O_2 sensors are monitoring cycle performance and operator safety

MORE CONTROL

▶ The Control System is based on the most advanced versions of Siemens or Allen Bradley aligned with 21 CFR part 11 and GAMP5

▶ Our cutting-edge SCADA (Supervisory Control and Data Acquisition) system offers seamless integration with your MES (Manufacturing Execution System) through OPC-UA

▶ An automatic leak testing is executed according to ISO 14644-7

MORE CLEVER

▶ The Transfer Airlock is complete of an ultra-clean and flexible sliding trolley

▶ Improve ergonomics with sliding shelves

▶ Collect process drains safely in a wheeled tank

▶ Stay informed on the machine status watching the light bar

ISO**care**

STERILITY TESTING ISOLATOR

STERILITY TESTING is the last demonstration of the state of control (CCS effectiveness) in sterile manufacturing, which confirms successful completion of aseptic processing before batch release.

According to cGMP and PIC/s, Sterility Testing should be performed under aseptic conditions, which are consistent with the environment for the aseptic manufacture of pharmaceutical products.

Sterility Testing Isolators are the most robust technology for minimizing microbiological contamination. ISOCARE isolator technology is designed for aseptic and aseptic-toxic operations, ensuring high-grade protection for products and operators in compliance with cGMP standards.

ISOLATION TECHNOLOGY DEDICATED TO YOUR PROCESS

▶ ISO**care** : Sterility Testing Isolator and QC.

▶ ISO**cell** :Cell & Gene Aseptic Processing (ATMP).

▶ asepti**care**: Multi-purpuse for Sterile Processing - Sterile Formulation - Component Preparation - Small Batch Fill Finishing

Configurations can be customized with selected modules to optimize process flow.

CARE FOR

QUALITY

▶ ISOCARE represents the most robust answer to the GMP requirements, in terms of sterility assurance, conceived following a real QbD approach and meticulosly crafted to ensure highest level of protection and safety in pharmaceutical aseptic processes.

SAFETY

▶ We make sure your process comply with highest hygenic standards and it's controlled by the highest level of automation.
The integrated decontamination system guarantees ultra-rapid 6-log microbial reduction, increasing time available for your process.

PROCESS

▶ Take advantage of our modular construction which adapts to your individual requirements and spaces – or - use our Plug&Play predefined configurations to speed up your time to market.

ENVIRONMENT

▶ ISOCARE is extremely compact and it's suitable to be installed into an EU-GMP ClassD environment, increasing accessibility and reducing dramatically operational and energy costs.

OPERATORS

▶ We implemented a Human Centric Design to maximize comfort for the operator during operations, improve ergonomics and minimize strain and fatigue.
Less stress – more focus on the process details which matters the most.

PARTNERS

▶ We stand by you during project development with dedicated Project Management-Customer Care - Qualified Validation experts. Our Training Activity Center (TAC) is always open for our customers. We are globally local so you can have quick interventions, local resources and spare parts.

DESIGNING RESULTS

iwt ®

COMPANY WITH
QUALITY SYSTEM
CERTIFIED BY DNV
ISO 9001

COMPANY WITH
ENVIRONMENTAL SYSTEM
CERTIFIED BY DNV
ISO 14001

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