skan

Filling line

Customized Solutions

The first step towards success – Creating individual solutions together

Our customers' needs are the focus of every process design. That is why it is important for us to understand and analyze these needs. Together with selected partners, we transfer these requirements to our concepts, resulting in practical and efficient systems for every challenge.

We design the best processes for every application, container type and process for aseptic filling, including freeze drying. Our unique technology for isolators and filling equipment allows robust designs for a reliable system that meets your individual product and environmental requirements.

1 SKAN Group – The best partner and technology

For more than 30 years, SKAN has been promoting isolator technology with innovative techniques and solutions for validatable decontamination processes. As a Swiss company, we are proud to be the global market and technology leader for isolators, clean room devices and decontamination processes for aseptic production in the global biopharmaceutical market.

Aseptic isolators have become the standard worldwide for all types of aseptic and aseptic-toxic applications, from small-scale filling to fully automated production processes on a large scale. Thousands of satisfied customers worldwide trust in our high quality standards from the first engineering step to the final validation. Our focus is always on the highest level of product safety and therefore patient safety. SKAN isolators combine the best technologies for modern decontamination and increase both the safety and productivity of your processes.

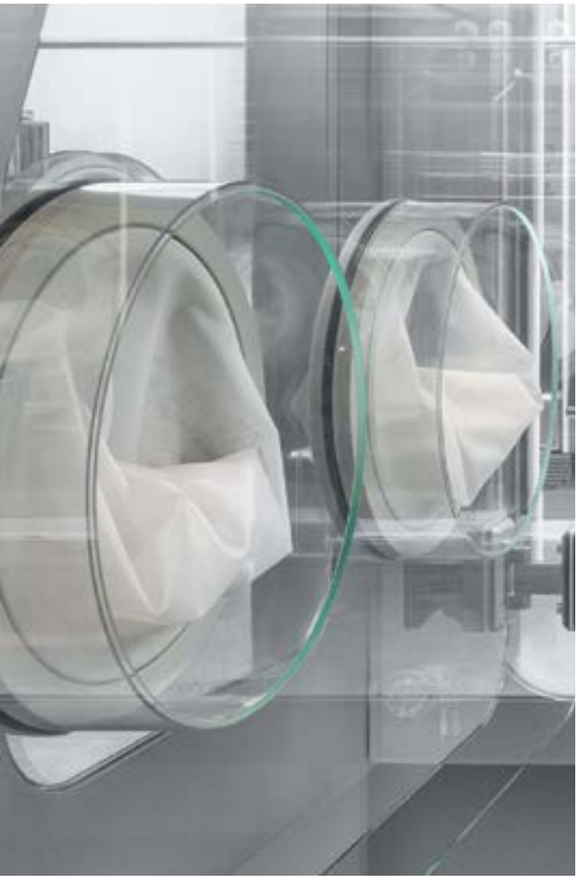
SKAN AG, Switzerland

2 The air handling system – It makes the difference

Air treatment is essential to product safety and is a key feature of the isolator. HEPA filtered and conditioned air guarantees that the isolator remains aseptic during production, as required by official regulations. This includes the first air principle with unidirectional air flow at a speed of 0.45 m/s. The particle and microbiological limits in the working chamber also meet the required product protection with EU GMP Grade A (ISO 5) according to EN ISO 14644-1.
The air handling units (AHU) are usually positioned in the technical area, while the isolator itself can be placed in an EU GMP Grade D (ISO 8) environment. Depending on the application, the supply and exhaust air is not only HEPA filtered, but also dehumidified and cooled. For safe filtration, filter fan units are built into the positive filter plenum and prepared for regular integrity checks with the DEHS aerosol. All fans responsible for the differential pressure are regulated. Fans for the recirculating air can be adapted to provide the required unidirectional air flow over the entire production zone together with the air distribution membranes according to EEC-GMP and cGMP requirements. Integrated nanox® catalysts break down the hydrogen peroxide (H_2O_2) in a once-through process at the end of the decontamination cycle. As a result, the required air can be supplied by the surrounding space and safely returned to the same room with guaranteed safety for the operator. This environmentally friendly method eliminates the need for complex piping to the outside of the building and allows the treated air to be reused several times. "The nanox catalysts allow us to have a direct linkage to the cleanroom. This means an air flow of net zero, so that the isolator doesn't affect the room pressure. What goes in comes out – at all times!"

HEPA filter fan

3 The double door system – Perfect distribution



Double door system

Increased distance between the two doors of the double door system enables the best air distribution while still providing maximum accessibility and visibility. The defined air flow of 0.45 m/s generates thousands of cubic metres of air that must be circulated. Thanks to the double door system, this large volume of air can be efficiently removed, filtered and reused without cross-currents or turbulence occurring in the isolator. Thanks to the double doors, no external air ducts are required, which enables good and direct access to the isolator chamber. The hinged doors are kept in place by gas pressure springs and can be opened easily and safely. For optimum durability the doors are made from solid toughened safety glass. They are easy to open and clean. Inflatable gaskets and position monitoring guarantee safe operation.

4 skanfog® – Clever decontamination technology

The integrated skanfog® H_2O_2 decontamination system with our patented nanox® catalyst has established itself as the gold standard on the market. Our performance guarantee provides very short and qualified cycle times of less than one hour (typical cycle, including non-absorptive load materials) including aeration down to 1 ppm residual H_2O_2 concentration. This safe and robust decontamination system is key to a reliable and reproducible 6 to 10 log reduction. After the automatic leak test the chamber is preconditioned, then H_2O_2 is injected through numerous strategically placed nozzles for even and rapid distribution followed by efficient aeration.

skanfog®

5 Automation system – Convenient and reliable

SKAN automated solutions are developed and validated in-house according to current GAMP5 category guidelines and are CFR 21 Part 11 compliant.

Established PLC Siemens or Allen Bradley PLC control systems are used on Beckhoff touchscreen monitors. Supervisory Control and Data Acquisition (SCADA) provides full data integrity, reporting functions, Active Directory and audit trail functionalities.

Electronic records and signature, OPC interface and thin client technology with customer server can be provided as options. Customized automation solutions are also available upon request.

SKAN automated solutions are developed according to current GMP and fulfil regulatory requirements.

- ⟶ cGMP guidelines, CFR 21 Part 11, EndraLex Volume 4
- ⟶ Supervisory Control And Data Acquisition (SCADA)
- ⟶ PLC - Siemens or Allen Bradley
- ⟶ HMI - Beckhoff Industrial PC
- ⟶ Beckhoff touchscreen monitor
- ⟶ Active Directory
- ⟶ Decontamination report
- ⟶ Batch report
- ⟶ Campaign report
- ⟶ Audit trail functionalities
- ⟶ Electronic records
- ⟶ Electronic signature
- ⟶ OPC interface

6 Interfaces with dry heat tunnels and ebeam systems

Each isolator has numerous interfaces to upstream and/or downstream machinery for transporting products, accessories or primary packaging material. The interfaces vary according to the object being filled. Vials, for instance, must be washed, sterilized and depyrogenated using a dry heat or depyrogenation tunnel before being transferred into the decontaminated isolator. The tunnel is directly connected to the isolator and can be completely closed during isolator decontamination and also during the cooling zone sterilisation of the tunnel.

Nested objects in tubs can be transferred into the decontaminated isolator through an ebeam. The ebeam (Electron Beam Tunnel) uses electron energy for continuous surface decontamination in high-speed aseptic filling lines, ensuring the highest standards of hygiene while providing significant operational cost savings in component packaging. The safe and compact ebeam system is equipped with a multi-part transport system that safely transports ready-to-use containers through a tunnel with three long-life electron emitters. The integrated decontamination system guarantees a safe and short decontamination cycle for the inner surfaces of the ebeam. As the use of ebeam reliably reduces the bioburden on surfaces before objects enter the aseptic area, it can be seen as state-of-the-art equipment for high-speed filling of RTU objects.

ebeam: middle section emitters

ebeam: open front

7 Environmental monitoring – Proof of quality

Environmental monitoring (EM) is a measure to verify the airborne cleanliness in terms of viable and non-viable particles as per cleanroom classification. To ensure a robust process, regulators encourage oversight over the entire manufacturing process. For Grade A zones, particle monitoring should be performed throughout the critical processing period. Risk assessments of aseptic filling lines indicate the frequency and locations of environmental sampling.

We have predefined monitoring solutions for viable and non-viable particulate sampling with integrated decontamination. SKAN solutions are available from many suppliers and can be adapted to the needs of our customers.

Integrated viable air sampling atrium

8 Clean interior design

The interior of an isolator is very important and must be considered during the design phase. The interior must allow proper and safe H_2O_2 decontamination within a short period of time. A risk-managed cleaning strategy must therefore be implemented in parallel with the design process, especially when treating active ingredients. Cleaning before and after each process will prevent surface or airborne cross-contamination during product changeover. The material should be durable for surface analysis and clean mapping. SKAN's experts design based on an intimate understanding of the process and practical experience.

H2O2 dosing unit – one-pump system

9 Material transfer

RTP – Rapid Transfer Ports

Something is always being processed, produced or bottled within an isolator. It is very important that sterile materials such as filling needles, pumps, stoppers, petri dishes and any other materials can be aseptically transferred into the isolator. This is the only way of protecting the aseptic area throughout the entire process. The Rapid Transfer Port (RTP) is a type of transfer lock to which a pre-sterilized container can be docked from the outside. An interlock security mechanism guarantees correct manipulation. With a clever door-to-door system, the inner door can be opened with the glove port nearby and the product safely transferred into the isolator. At the same time, materials or any waste can be transferred via the container to the outside. After the inner door is closed and locked again, the container can be undocked safely. In some cases, a stopper processing system can dock directly with the RTP and safely transfer processed, sterile stoppers into the filling line isolator.

Component infeed using an RTP container

SARA – SAfe and RApid Transfer Airlock

Depending on your specific process, quick and easy aseptic transfer into the aseptic processing area might be required while the isolator itself stays decontaminated. The attached rapid transfer airlock is the perfect solution. It can be attached wherever it is needed and has enough space for the transfer process. Thanks to the independent decontamination, the process taking place in the isolator is not interrupted which has a positive impact on your production efficiency and quality.

SARA

SARA integrated in spectra

MTI – Material Transfer Isolator

The MTI Material Transfer Isolator is our smallest two-glove isolator with integrated skanfog® technology. The MTI is a smart solution for all types of aseptic interfaces and manipulations.

This independent and autonomous isolator system features fully automated surface decontamination with H_2O_2 nebulization technology ensuring safe, fast and validatable aseptic processes and transfers in record time. Compact and optimized with a built-in nanox® catalyst, the MTI can fit into any laboratory environment even without exhaust ducts to the outside.

MTI

Open MTI

The distinctive features of the MTI make the difference

- ⟶ EU-GMP Class A (ISO 5) certification of the manipulation chamber for surface decontamination
- ⟶ Integrated skanfog® technology for fast and reliable decontamination cycles
- ⟶ Integrated SKAN nanox® catalyst for autonomous operation of the isolator
- ⟶ Built-in AT-Port™ system for safe connection of aseptic liquid transfers (optional)
- ⟶ Integrated rapid transfer ports (RTPs) for safe and aseptic loading of containers (optional)
- ⟶ Shelf mounting is available on request

10 Robotic solutions

SKAN offers a variety of solutions for all types of manufacturing processes and applications. The customized isolators are not only used for product protection, but also for operator protection in aseptic processes. To ensure the highest possible level of safety for product and operator, intervention is reduced to a minimum by robotic equipment. The process machines and robot systems used in the isolator are almost unlimited and can support any individual process in an optimal and operator-friendly way. Because robots are indispensable, SKAN has created the best robotic systems for integrated processes together with reliable partners.

Robotic handling and transfer of a potent powder in an aseptic isolator.

11 WirelessGT 2® – Reliable glove integrity testing

The WirelessGT 2 is the most advanced and fully automated glove testing system on the market. The test system complies with cGMP specifications regarding pressure decay measurement for glove testing systems in isolators and RABS in the pharmaceutical industry. All functions necessary for reliable and fast glove testing are integrated in the battery-powered test cover and do not require any hoses or wires. The system automatically monitors the pressure loss of the glove or sleeve assembly over an individually definable time in accordance with a user-specific test recipe. This system reduces glove testing cycle time and generates reliable test results on a scientific basis with documented reports.

The innovative and hygienic design allows simultaneous testing of multiple installed gloves a grade B, C or D cleanroom. The rechargeable lithium ion batteries with active battery management system allow a minimum of 20 testing cycles with a testing pressure up to 3000 Pa and can detect holes larger than 100 µm.

The system includes operator access management (Active Directory) and maintains a standardized data interface via OPC (DA, AE and UA) to create a customized audit trail. It is 21 CFR Part 11 compliant and IP54 certified. For more information, please refer to the dedicated brochure.

WGT 2

Glove testing

Local and global support

SKAN production isolators are customer-specific but have predefined interfaces to our preferred filling machine manufacturers. We work closely with them throughout the life cycle of the product.

One joint cross-company development resulted in a unique line for vial processing. This ingenious line, which integrates the filling machine and isolator as one system, revolutionized the pharmaceutical industry and earned us an award for the best integrated filling line. Various lines with maximum speeds and standardized isolator technology are available.

All these developments are based on our scientific principles for process validation of isolator systems. Every SKAN isolator builds on the work of outstanding researchers and laboratories specializing in biological indicators, H_2O_2 trace analysis, cleaning validation and process design.

Worldwide isolator support

SKAN offers professional support to ensure that your equipment is operating at maximum productivity and reliability. The development of comprehensive maintenance programmes and services covering all aspects of SKAN equipment was inspired by the decades of hands-on experience acquired by SKAN's experts.

Our certified technicians perform precise recalibrations and repairs as well as modification requests on site, to maintain the qualified status of your equipment. SKAN's microbiological re-qualification verifies the effectiveness of the decontamination process and guarantees the safety of the workplace, professionally and reliably.

SKAN's experienced service and maintenance experts will take care of any problems or issues that may occur during the life cycle of your installation. Our experts provide specific knowledge and know your plant in detail, so that malfunctions and failures can be solved quickly and easily. Corrective maintenance is offered both as an on-site service and as remote support.

SKAN's digital support services

SKAN offers two cutting-edge digital technologies to enhance its comprehensive services:

Augmented Reality (AR): SKAN's AR technology is preferred for services and maintenance and allows our experienced technicians to be virtually on site and analyze problems in a targeted manner.

Virtual Reality (VR): SKAN's VR technology is ideal for training purposes. Through virtual simulations of isolators and process flows, plant operators can easily acquire and refresh knowledge without risk.

Superior documentation

Each project is supported by an experienced SKAN project team to achieve the best possible results in a short time. We attach great importance to the quality of the documentation of each inspection. All our products and projects include the required GMP design and validation documents defined in our Quality Project Plan (QPP).

At SKAN, this includes the Factory Acceptance Test (FAT). Our qualification and validation service includes the IQ and OQ protocol and report as well as the microbiological qualification and validation package.

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