



## **SafeFlex Isolator System**

Containment-Level  $\leq$  OEB 5 ( $<1\mu\text{g}/\text{m}^3$ )

### The SafeFlex Isolator – the flexible solution for closed processes

#### Flexible containment solution



Isolators are used to protect the environment or the processed product. A very well-planned flexible containment isolator comes very close to a stainless-steel isolator in terms of protection and can offer various advantages depending on the application.

This can be especially true for smaller product quantities, frequent product changes and frequent changes in process steps. Flexible containment can be converted quickly, which allows the operator to save time and money.

#### Possible uses for SafeFlex Isolators:

- Sampling
- Weighing
- Lyophilization
- Filter change
- Dismantling
- Emptying
- Reactor feeding / filling

#### Possible uses for local containment:

(direct docking to the process equipment without its own frame)

- Filter change
- Sampling
- Enclosure of cleaning equipment (CIP and WIP)
- Maintenance purposes / dismantling



Scan the QR code and watch directly the video

#### The advantages of the SafeFlex Isolator:

- High product and personal protection
- Easy handling
- Universal usability
- Foil with high tear resistance
- High quality
- Lower investment costs compared to rigid systems
- Elimination of cleaning and validation costs
- Integrable in existing systems
- Gamma or x-ray sterilization possible
- Containment can be done quickly and can be adjusted flexibly afterwards

### The SafeFlex Isolator – the flexible solution for closed processes

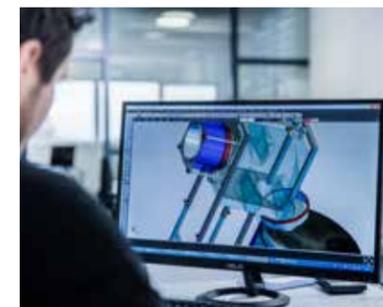
#### Quality »Made in Switzerland«



Lugaia is pushing the development of comprehensive Containment Solutions – from the idea of the ergonomic study all the way through to making more complex isolator systems. Our infrastructure enables us to offer standardized solutions in different

quality grades as well as customized solutions, manufactured in highest quality and adapted to local customer requirements. Our experience in the field of containment as well as the steadily growing requirements of various industries

form the basis of our continuous innovation processes. In the end, this also guarantees the »Made in Switzerland« rating for precision, quality and reliability.



#### Design & Engineering

Custom concepts and solutions are developed using 3D-CAD software. Customer interfaces can thus be flexibly taken into account.



#### Manufacturing

At qualified manufacturing facilities, all products are produced under consideration of the specified clean room requirements. Validated processes and well trained staff stand for high quality products.



#### Pressure Test

After production, all SafeFlex Isolators are checked for leaks and then receive approval for delivery.

## SafeFlex Isolator

The parts



The flexible isolators can be **customized to customer requirements and needs** and adapted to local conditions in terms of dimensions and connectivity options such as ergonomic requirements.

The basis for the isolator system is provided by the **stainless-steel base frame**. This is available in different configuration options e.g. with a stepless height adjustment, storage options for equipment, platforms, different grounding points such as casters and stand.

The flexible isolator is made using easy-to-use tabs and snap fastener.

The magnetic base plate on the bottom of the isolator provides a fixed and leveled platform.

The optionally available **Lugaia ventilation technology** will carry out a pressure test. After operation approval, the dust-free docking of containers can be started. In operating mode, the isolator is in negative pressure with constant air exchange. After finishing a production batch and necessary change of the isolator, the negative pressure will be interrupted and the enclosed air will be evacuated. The isolator can then be removed and disposed.

The isolator can be equipped with different **customer-specific** dockings e.g. with special gloves and CLS Continuous Liner for the inward and outward transfer of equipment and product. There are also docking options for containers such as drums, connections for transfer systems (SafePort TransferBags or RTP Ports) and interfaces for media feed. Direct machine and system connection options can also be implemented on request.

## SafeFlex Isolator

The components

### The SafeFlex Isolator – user friendly and flexible

Combines all advantages of Lugaia's precision products and cutting-edge technology



#### Snap fastener and zippers

The tabs with incorporated snap fasteners allow for an easy and quick attachment to the base frame of the isolator. Due to the flexible and tear-resistant SafeFlex Foil, tension in the material is guaranteed (wrinkle-free field of vision). The inside of the isolator can be equipped with an integrated zipper. A zipper can also be integrated into a side wall to facilitate inward and outward transfer of large equipment.



#### Magnetic Base Plate

The stainless-steel base frame has a rustproof, magnetic work platform. The bottom of the isolator is also equipped with a base plate from the outside. Thus, it offers a fixed work surface (especially in negative pressure) as well as additional reinforcement.



#### Filter Unit H14

Each isolator comes with at least one H14 filter which allows the system to breathe. The filter cartridge is directly incorporated in the isolator film. Additional filters are required at the use of Lugaia ventilation unit with optional leak test and air exchange. These filters come delivered with appropriate certificates.



#### Connect the container

Drums in various dimensions can be docked or exchanged to the isolator free of contamination by means of Double O-Ring technology.



#### Media Feed

The media is supplied via special interfaces in the isolator foil. When dismantling the isolator, it is possible to undock them without contamination. (power cables, air connections, connections for liquids, etc.)



#### Foil Liner

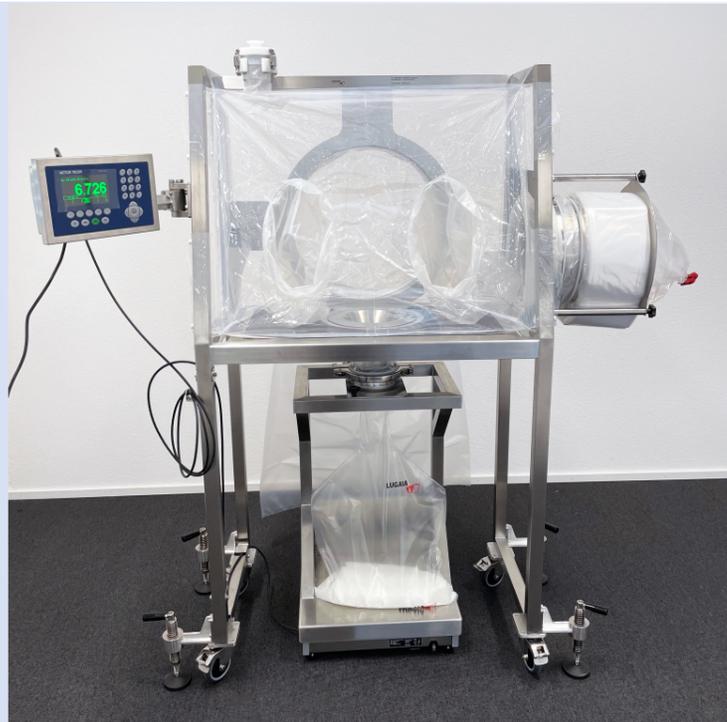
The CLS Continuous Liners serve as 2-way locks for product, equipment and waste. The assembly, change and dismantling of the Continuous Liner at the isolator takes place without contamination.

## SafeFlex Isolator

Customized special solutions

### Flexible Isolator

Containment for handling OEB 5 substances



#### Existing dispensing isolator for a pharma-customer

Using the single-use isolator, you can weigh a wide variety of product out of various containers required for production. The mobile device will be installed and used when necessary in the respective production facility, it can be equipped with Continuous Liners, TransferBags and SafePort Bags.

### Ventilation technology

#### Mobile ventilation device

The mobile ventilation unit is equipped with PLC-Software and is operated via a HMI touch panel. The complete circuit and control technology is built into the equipment cabinet. The ventilation unit is available in standard or ATEX versions. In both versions, the equipment cabinet is made entirely of stainless steel.



#### The functions

##### 1. Pressure test

- Automatically running pressure test according to the specified parameter

##### 2. Working mode

- Vacuum operation
- Automatically running inerting process
- Possible system monitoring over O<sub>2</sub> measurement
- Parameters will be adapted to the process

##### 3. Evacuation Mode

- Evacuation of the isolator system via regulated vacuum operation

## SafeFlex Isolator

Customized special solutions

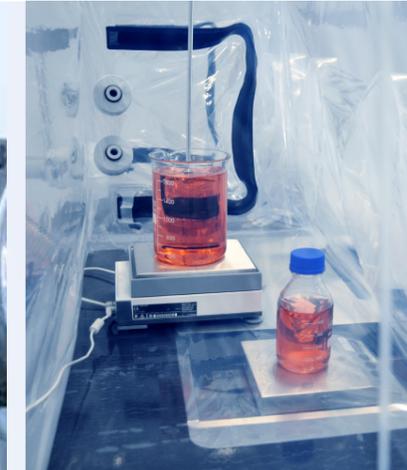
### Individual special solutions

Specially adapted to your needs



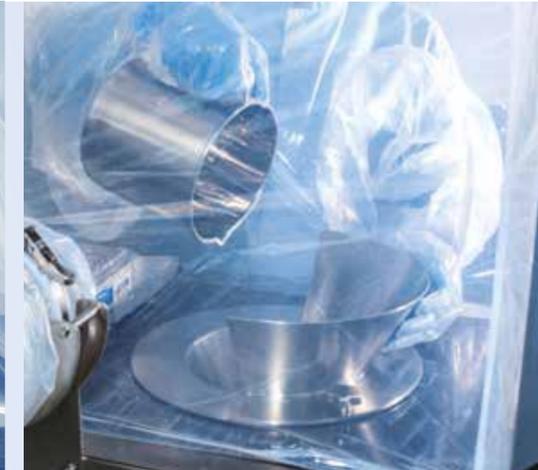
#### Ease of Use

The properties of the SafeFlex Foil allow a good view inside, as well as optimal freedom of movement.



#### Integrable systems

Depending on the application and needs, customer equipment such as scales and stirrers can be provided and placed inside.



#### Accessories

To make handling easier, you can choose numerous accessories



#### Custom made products for special tasks

No production facility is the same. Almost every containment measure must therefore be manufactured individually exactly fitting to the local requirements. With this we are able to design and manufacture an individual solution according to customer wishes, practicality and requirements.

We develop and adapt to your needs and requirements, for example: **Containment Solution for sampling, filter change and dismantling** but also for **cleaning and maintenance purposes**.



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**Our product overview:**

- Continuous Liner System CLS / CLCC
- SafeSeal Closure System
- TransferBag System
- SafeFlex Isolator System

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