



# **Features**

### **Operating mode**

Operating modes are visible by different colored internal lighting (white, blue, red).

#### Airlock

The airlock is equipped with a shelf and can be placed to the left, right or on both sides of the isolator.

#### Space-saving design

The working chamber is available in two sizes, with either two or four glove ports.

The compact design means it will fit through standard doors and in lifts.

All operation and maintenance openings are accessible from the front.

#### H<sub>2</sub>O<sub>2</sub> station

Fully integrated decontamination system in each chamber. Commercially available hydrogen peroxide (H2O2) 35% can be stored safely in the isolator. Micro-nebulisation guarantees fast, reproducible decontamination cycles which can be validated.

#### H14 HEPA FIPA filter cartridge

Patented SKAN technology for safe, simple filter changes.

H14 filters, each with a filtration efficiency of 99.995 %.

## Display

skan

pure<sup>2</sup>

9" Siemens color touch screen with local user administration. The Siemens controller represents the current industry standard, including trend monitoring, batch log creation and optional audit trail.

# Housing and design

ABS polymer - a widely used, strong and durable standard material for exceptional design in the laboratory.

#### **Glove test**

The custom-configured SKAN glove testing system is available as an option. Glove ports compatible with WirelessGT2.

#### nanox catalytic converter

nanox catalytic converter technology reduces aeration time and allows autonomous operation without having to connect to the building's air exhaust system.

Built-in catalytic decomposition of H<sub>2</sub>O<sub>2</sub> (≥ 99.97%) allows direct exchange with ambient

The pure<sup>2</sup> isolator comes with double HEPA

#### Our experience - your advantage

SKAN combines extensive knowledge of laboratory safety cabinets and isolators.

#### Standards and certification

- CB scheme in accordance with IEC 61010-1:2010, meeting international, mutually recognised IECEE standards for product safety for electrical equipment. Tested, certified and monitored by certified body Eurofins Product Service GmbH.
- GS mark for the type examination under DIN 12980:2017-05 in accordance with the requirements of the German Device and Product Safety Act (ProdSG, section 22). Tested, certified and monitored by certified body TÜV NORD CERT GmbH.
- → Machinery Directive 2006/42/EC
- → EMC Directive 2014/30/EC
- EN 12469 (performance criteria for microbiology safety cabinets)
- ISO 14644-3/7 (test methods / clean air hoods, glove boxes, isolators and mini-environments)







# **Applications**

- → Sterility testing
- → Biosafety
- → Cell and Gene
- → Pharmaceutical manufacture



## **Sterility testing**

- → Plug-and-play design
- Working chamber corresponds to GMP Grade A / ISO 5 with unidirectionalairflow
- Optional integration of sterility testing pump (Millipore or Sartorius)
- FDA 21 CFR Part 11 compliance through Siemens controller



#### **Cell and Gene**

- Flexibly adapts to your work and manufacturing process
- Suitable for fast material transfer when processing cell cultures
- Assured operator and environmental protection, with optional H<sub>2</sub>O<sub>2</sub> decontamination
- Contamination protection through GMPcompliant unidirectional air flow



# **Biosafety**

- Systematic protection against hazards when processing biological agents
- Safe and complete containment thanks to the selectable negative pressure operation
- Assured operator and environmental protection, with optional H<sub>2</sub>O<sub>2</sub> decontamination
- Reduction of microbiological load

# Pharmaceutical manufacturing

- Suitable for aseptic and aseptic-toxic applications (e.g. CMR substances)
- Improved patient safety through compliance with GMP requirements
- Complies with GMP and FDA 21 CFR Part 11 for processing electronic data records
- Optional configuration for the integration of filling equipment





# pure<sup>2</sup> specifications

# Your requirement

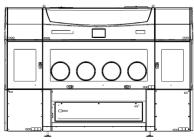
- Safe containment system corresponds to GMP Grade A / ISO 5 with unidirectional airflow
- → Wide range of applications
- → Fast, automated H<sub>2</sub>O<sub>2</sub> decontamination
- Compliance with applicable regulatory and standards requirements
- Excellent ergonomics and working conditions combined with maximum safety

#### **Our Solution**

- The pure isolator is intended for aseptic and aseptic-toxic applications
- Sealed containment system provides safety even when working with high-risk or highly potent products
- → Faster, safer H<sub>2</sub>O<sub>2</sub> decontamination cycle thanks to patented skanfog technology
- Spacious airlock and fast transfer increase productivity
- Thanks to the built-in SKAN nanox catalytic converter, no connection to the building's air exhaust system is required
- → Simple plug-and-play installation process
- → Modular, space-saving design
- Worldwide service and support network through subsidiaries and partners







Туре		2-glove working chamber	4-glove working chamber
Турс		2 glove working chamber	4 glove working chamber
External dimensions [w x d x h] with 2 airlocks	[mm] [ft, in]	2811 × 955 × 2277 9'-3" × 3'-2" × 7'-6" (see diagram above)	3301 × 955 × 2277 10'-10" × 3'-2" × 7'-6" (see diagram above)
External dimensions [w x d x h] with 1 airlock	[mm] [ft, in]	2196 × 955 × 2277 7'-2" × 3'-2" × 7'-6"	2683 × 955 × 2277 8'-8" × 3'-2" × 7'-6"
External dimensions [w x d x h] working chamber alone	[mm] [ft, in]	1581 × 955 × 2277 5'-1"×3'-2"×7'-6"	2065 × 955 × 2277 6'-8" × 3'-2" × 7'-6"
Working area [w x d x h]	[mm] [ft, in]	1410 × 715 × 629 4'-8" × 2'-4" × 2'-1"	1895 × 715 × 629 6'-3" × 2'-4" × 2'-1"
Height of work surface	[mm] [ft, in]	970 (± 50mm) 3'-2" (± 2")	970 (± 50mm) 3'-2" (± 2")
H <sub>2</sub> O <sub>2</sub> type	[L]/[%]	Standard: 1.0 / 35, optional: 2.5 / 35	
Operating pressure	[Pa]	-60 or +60 (please specify when ordering)	
Air velocity Downflow laminar airflow	[m/s]	0.45 +/- 20% 0.25 (standby)	
Air consumption isolator / airlock	[m³/h]	250 - 650	
Working area material	Туре	Stainless steel AISI 316L (EN 1.4404) Ra ≤ 0.8 μm	
Housing material	Туре	ABS polymer	
Window material	Туре	Double-glazed safety glass	
Exhaust (double filtration)	Type, filter class	HEPA H14 filtration (SKAN FiPa) (standalone operation, connection to building's air exhaust system not required)	
Airlock filter	Type, filter class	Intake air HEPA H14 filter plate / exhaust air HEPA H14 SKAN FIPA	
H <sub>2</sub> O <sub>2</sub> catalytic converter	Туре	SKAN nanox, patented SKAN technology	
Operation	Туре	Built-in controller with 9" colour touch screen, GAMP 5 Category 4	
Interfaces	Туре	USB & Network	
Illumination	[lx]	> 800 in the working chamber	
Air supply pressure	[bar]/[Nm³/h]	6-10 / 8 -22, class 1.3.1 (as per ISO 8573-1:2010)	
Sound level	db (A)	max. 65	
Power supply (single phase)	[VAC]/[Hz]/[W]	220 - 240/50 - 60/max. 3500	
Weight	[kg]	2 glove working chamber 4 glove working chamber Airlock	400 700 250



**SKAN AG** Kreuzstrasse 5 4123 Allschwil, Switzerland +41 61 485 44 44, info@skan.ch

**SKAN Stein AG** Industriestrasse 3 4332 Stein, Switzerland +41 62 885 03 00, info.stein@skan.ch

**SKAN Deutschland GmbH** Nickrischer Straße 2 02827 Görlitz/Hagenwerder, Germany +49 358 223 789 0, de.info@de.skan.ch

**SKAN US, Inc.** 7409 ACC Blvd., Suite 200 Raleigh, NC 27617, USA +1 919 354 6380, us.sales@us.skan.ch

SKAN Japan 5194-61 Katsuren-Haebaru Uruma-shi Okinawa 沖縄県 904-2311, Japan 日本 +81 98 934 9922, jpskan@skan.ch

**SKAN do Brasil** Green Valley Alphaville Av. Andromeda, 885 - 28th Floor, Office 2823 Barueri, CEP: 06473-000, São Paulo - SP – Brazil +55 11 4191 9493, skandobrasil@skan.com

**Aseptic Technologies SA** Rue Camille Hubert 7-9 5032 Gembloux /Les Isnes, Belgium +32 81 409 410, info@aseptictech.com

