



**Center of
Competence for
Isolator Technology &
H₂O₂ Decontamination**

**Approved Validation
Isolator-Process Solutions**

**Statistically based
H₂O₂ Decontamination**

**Scientifically founded
Qualification Strategy**

**Professional
Customer Support**



Your Aim

- **A safe and easy to validate isolator solution**, with H₂O₂ decontamination process, meeting your and the requirements of the authorities e.g. FDA, MCA, IKS.
- Not only assembled systems but a **complete isolator solution**, which forms **a entity** with the decontamination process.
- A H₂O₂ decontamination based on a **scientifically founded process development**.
- A **statistically significant definition** of the process performance and boundaries.
- A clear and **transparent cycle development** methodology for decontamination, GMP-conformed documented.
- No waste of time with **problems of D-value determination and suitability of biological indicators** by using tested bio indicators with proven specifications.
- Save time by using **scientifically based reference studies** regarding critical questions of authorities.
- Not a **surprise during qualification** but a safe and fast testing of your requirements without any deficiencies of information.
- **Professional and competent support** and advice with pragmatic and validatable solutions.

All in all:

You don't want **just an isolator and a H₂O₂ System** in what you have to invest a significant amount of time.
You expect a **professional and complete Isolator Process Solution** which fast and safe meets your requirements.

You want to produce not to experiment



Our Solution

Validatable, integrated Isolator Process Solution

- dedicated customized as one unit for your process
- complete from DQ to PQ

Statistically based H₂O₂ Decontamination Process

- numerous FDA, MCA, IKS approvals
- scientifically founded process development
- statistically significant definition of process performance and boundaries
- based on accepted reference studies
- fast, safe, uncomplicated

Scientifically founded Qualification Strategy

H₂O₂ Cycle Development

- internationally successful utilization
- highly accepted by the authorities
- published in international scientific papers

H₂O₂ Reference Studies

- influences of surface materials on the decontamination effect
- transferability of results to different systems
- D-value and suitability studies of biological indicators
- internationally published and accepted

Microbiological Qualification

- GMP-conformed realized and documented

Professional Customer Support

- competent and scientific support
- in house GMP-lab including reference isolator system
- fast, pragmatic, concrete

Your Profit

- an isolator process solution meeting exactly your requirements
- a fast validation without any deficiencies
- traceable and scientifically based processes
- time saving during qualification
- high acceptance by authorities e.g. FDA, MCA, IKS
- professional support and backup
- fast requalification without any problem
- massive time- and cost savings for your isolator project



Integrated Isolator-Process Solution

SIS 700 System

The integrated Solution for an aseptic Isolator System

The integrated SIS 700 Process is a highly efficient H₂O₂ decontamination method to guarantee aseptic environmental conditions.

This integration method was developed by the R&D department of Skan AG to ensure the optimal integration of the H₂O₂ decontamination process into an isolator system.

Because of this integrative view on isolator systems and processes Skan AG is able to supply complete customized solutions.



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SKAN Filling Isolator with integrated SIS 700 H₂O₂ decontamination process.



H₂O₂ Decontamination Process

SIS 700 System

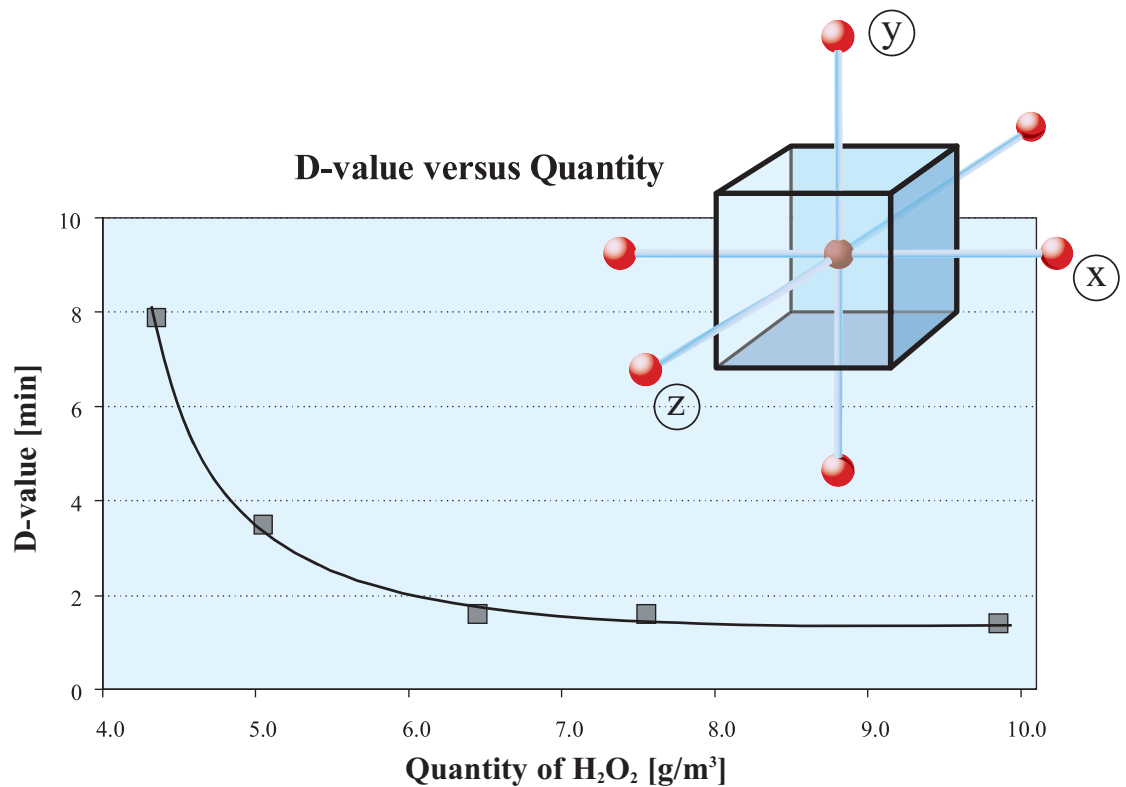
A consequent Process Development as Basis for a smooth Qualification

The H₂O₂ decontamination process SIS 700 is established in the international market and successfully approved by the authorities e.g. FDA, MCA, IKS.

This process based on an unique process development which ensures a statistically significant correlation between physical process and microbiological result.

Studies of Skan`s R&D department conducted in a reproducible reference system, make basis data available for customized applications.

The transferability of the scientifically acknowledged basis data to customized systems, guarantees a safe and smooth qualification.





Qualification Strategy

From a customer specific H₂O₂ Cycle Development to a successful microbiological Qualification

The experts of Skan AG developed a transparent qualification strategy without any deficiencies suitable for all alternative sterilization processes.

All around the world the users of isolator technology call on the support of Skan experts to transition than safely and smoothly into the production phase of their system.

H₂O₂ Cycle Development

The development of the H₂O₂ decontamination cycle is realized and attended by Skan AG with a team of experts.

Based on a proven methodology the process parameters are determined and adjusted according to the customer specific requirements.

The systematic approach and complete documentation enables a transparent process development, which can be presented as a closed chain of arguments to the authorities.

Microbiological Qualification

At the final process qualification the expert team of Skan AG stand by with all established microbiological and physical test methods.

GMP- conforming documentation completes the traceability of the entire qualification.

The switch to the production phase of the isolator system is guaranteed safe and without problems.





Customer Support

The Competence Center of Skan AG develop integrated and complete solutions for your application

The R&D department of Skan AG conducts research focusing on application in a lab under GMP standards and work on different problems and questions together with the customer.

By active scientific publication and an open information exchange with customers an intensive know-how transfer is guaranteed and the comprehension for the process become absorbed.



On special questions concerning decontamination or individual problems regarding application of isolator technology the expert team of Skan AG offers competent advice and a comprehensive support.

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The Expert Team of Skan AG supports the whole Process Qualification

A team of specialists support the process qualification, flexible and responsible with the following services:

- Customized in house optimization of decontamination cycles independent of the supplier.
- Carrying out of process qualification based on a transparent and complete qualification strategy
- D-value determination of biological indicators and customer specific microorganisms in a reference isolator
- Suitability tests of biological indicators and materials for routine use in the isolator system



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Performance by Competence