



URGENT FIELD SAFETY NOTICE
SECUDRAPE SURGICAL GOWNS
Germ penetration performance
FSN/FSCA Ref. 26-SKP-VG01

By Sengewald Klinikprodukte GmbH, Adlerstr. 2, 83101, Rohrdorf-Thansau, GERMANY

For the attention of: Distributors of the medical devices listed below

Affected products and lot numbers:

Reference number	Product description	Lot	UDI-DI
464430	OR-Gown XXL (170) reinforced	11285082	04034393316482
464438	OR-Gown XL (150) reinforced	11288147	04034393145938

Description of product problem:

Two distributed lots of sterile surgical gowns labelled as high performance according to EN ISO 13795:2025 were tested in an accredited external laboratory for monitoring their compliance to the standard. While all other tests required by product specification confirmed compliance with the higher performance level, several samples taken from the full plot of tests for resistance to microbial penetration (wet) showed nonconforming results for the high-performance level, being fully compliant with the standard performance level.

Annex B.8 of EN 13795-1:2025 recognizes that this test method is inherently difficult to standardize and that inter-laboratory variability may occur.

To assess the discrepancy of test results, verification samples from the same lot, expanding to different lots and to different product references with same construction materials, were submitted to a second accredited external laboratory. All test results demonstrated compliance with the High-Performance specification limits and no out-of-specification results were observed.

Although verification testing confirmed compliance with the High-Performance criteria, Sengewald Klinikprodukte GmbH is issuing this Field Safety Notice as a precautionary measure, advising customers to regard the two affected lots as Standard Performance surgical gowns

Actions to be taken:

Use the gowns listed above only for procedures that are appropriate for standard performance gowns.

Sengewald Klinikprodukte GmbH

A company of STS Medical Group S.à.r.l. - Ein Unternehmen der STS Medical Group S.à.r.l.

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STS MEDICAL GROUP SENGEWALD
IMPROVING HEALTHCARE THROUGH EFFICIENCY

Sengewald Klinikprodukte GmbH regrets any inconvenience caused and appreciates your cooperation.

The competent authority in your respective country has been informed of this Urgent Field Safety Notice.

With kind regards,

Merixell Laguna

Deputy Vigilance PRRC

Sengewald Klinikprodukte GmbH

regaffairs-skp@stsmedicalgroup.com

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