

Aschaffenburg, 27 August 2019

From: Za-hu/pa
Authorized by: Zahn**REPORT**

Order No.: 18797/1 **Page 1 of 2 pages**

Client: Surgical Pouch Ltd.
8 Homestead Close
St Albans, Hertfordshire AL2 2AZ
United Kingdom

Date of order: 22 July 2019

Receipt of sample material: 25 July 2019

Origin of sample material: From the client

Purpose: Examination of a sterile barrier system material for micro-
bial barrier properties

(Dr. Derra)
Managing Director(Zahn)
Head of
Physical Material Testing

The present report refers exclusively to the samples as laid out therein. Information and statistical data on the results can be obtained on request.

Sample Material

For analysis the following sterile barrier system material was in hand:

Sample designation
Tri fabric, Product code: TX4140 3Ply, 150 gsm

Carrying out of the Tests

Examination period: 26 July 2019 to 26 August 2019

Determination of Germ Proofness under Humidity * and with Air Permeance*

The determination was performed according to DIN 58 953-6:2016-12, section 3 (germ proofness under humidity) and section 4 (germ proofness with air permeance). Each after sterilization by steam (134 °C / 5 min), by ethylene oxide (45 °C / 180 min / 650 mg/l / in cooperation with a partner institute) or by H₂O₂-plasma (Steriplas / 50 °C / 2 injections / in cooperation with a partner institute) the sample was contaminated with the test germ on the intended outside of the sterile barrier system (darker green material side / side A).

Result:

Germ proofness under humidity											
Sterilization - Test side	Number of CFU / agar plate										
	1	2	3	4	5	Σ					
Steam (134 °C) - Side A:	0	0	0	0	0	0					
Ethylene oxide - Side A:	0	0	0	0	0	0					
H ₂ O ₂ -plasma - Side A:	0	0	0	0	0	0					
Germ proofness with air permeance											
Sterilization - Test side	Number of CFU / specimen										
	1	2	3	4	5	6	7	8	9	10	Σ
Steam (134 °C) - Side A:	0	0	0	0	0	0	0	0	0	0	0
Ethylene oxide - Side A:	0	0	0	0	0	0	0	0	0	0	0
H ₂ O ₂ -plasma - Side A:	0	0	0	0	0	0	0	0	0	0	0

CFU = Colony forming unit

Comment:

The sample material submitted for analyses was tested on the darker green material side for its germ proofness under humidity and with air permeance each after sterilization by steam (134 °C / 5 min), by ethylene oxide (45 °C / 180 min / 650 mg/l) or by H₂O₂-plasma (Steriplas / 50 °C / 2 injections) and is evaluated as "sufficiently germ-proof" according to DIN 58953-6, section 3.8 and section 4.8.6.

The accreditation (Register no. D-PL-14160-01-01 and D-PL-14160-01-02) applies to the methods marked with * in the test report. End of report