

TECHNICAL DATA SHEET

SMS Wrapping Paper

PRODUCT CODE	:	4ASMS
RELATED STANDARDS	:	4A SMS are in compliance with the provisions of the Medical Device Regulation 2017/745 for medical devices.
INTENDED USE	:	Sterility assurance is a critical cornerstone of effective patient care. Therefore, the medical device wrapping is very important step of the sterilization process. Suitable wrapping techniques and proper wrapping material use provide sterile barrier during and after the sterilization process. 4A SMS paper is used to wrap materials to be sterilized.
OPERATION CONDITIONS	:	4A SMS papers are packing covers used in the sterilization along with the plasma. The sterilization conditions should be determined by the end user regarding to material to be sterilized.
FILTER CAPACITY	:	Filter capacity of the SMS after sterilization is one (1) year.
SPECIFICATIONS	:	

	SPECIFICATION	UNIT	TYPICAL VALUE
	SMS PAPER	BASIS WEIGHT	g/m ²
TENSILE STRENGTH MD		N/5cm	114
TENSILE STRENGTH CD		N/5cm	52,1
ELONGATION MD		%	96,2
ELONGATION CD		%	82,3
HYDROSTATIC HEAD		cm / wc	34
Resistance To Wet Microbial Transition - Barrier Index		BI	6
Resistance To Dry Microbial Transition		CFU	7
Linting		Log10	3,6
Microbial Contamination		CFU/100 cm ²	28
Particulate Matter Contamination		IPM	3,2

BACTERIAL FILTRATION EFFICIENCY (BFE)

Test Method: EKOTEKS 70 (In-House Method-Bacterial Filtration Efficiency Testing /Ref: TS EN 14683:2019 Medical Face Masks, Requirements and Test Methods (*))

A specimen of the mask material is clamped between an impactor and an aerosol chamber. An aerosol of Staphylococcus aureus is introduced into the aerosol chamber and drawn through the mask material and the impactor under vacuum. The bacterial filtration efficiency of the mask is given by the number of colony forming units passing through the medical face mask material expressed as a percentage of the number of colony forming units present in the challenge aerosol.

Test Flow Rate 28,3 L/min
 Test Flow Time 2 minute
 Sample Sizes 5 piece (10x10 cm²)
 Microorganism Staphylococcus aureus ATCC 6538
 Bacterial concentration (cfu/ ml) 5x10⁵ cfu/ ml
 incubation conditions 24 hour, 35°C ± 2°C
 Positive control average(C) 3.0x10³ cfu/ ml

TEST REPORT

RESULTS

TEST SAMPLE (T)	Number of Bacteria (cfu/ml)	Bacterial Filtration Efficiency (%B)
1	115	96,20%
2	110	96,30%
3	120	96,00%
4	126	95,80%
5	130	95,70%

$$B = (C - T) / C \times 100$$

%B: Bacterial Filtration Efficiency

C: is the mean of the total plate counts for the two positive control runs

T: is the plate count for the test specimen

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STORAGE AND DISPOSAL

: It must be boxed with polyethylene bags in as much as it shall not be damaged by external factors during storage and shipment. It must be kept away from toxic substances. Date of manufacturing and expiry date are stated on outer packing. Shelf life is 5 years after production date.

PACKAGING

: SMS papers are packed as below.

<u>Dimensions</u>	<u>Pieces in carton</u>
500 x 500	300
600 x 600	300
750 x 750	150
900 x 900	150
1000 x 1000	150
1200 x 1200	100

MANUFACTURER

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