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SUBJECT

Bacterial Filtration Efficiency (BFE)

CLIENT

3P Medical Device Pte Ltd 119 Neythal Road #01-01 Singapore 628605

Attn: Joseph Ong

SAMPLE SUBMISSION DATE / TEST DATE

26 Aug 2020 / 01 Sep 2020

DESCRIPTION OF SAMPLE

One sample described as below was received:

Product Name / Brand Name	Manufacturer	Lot Number
SURGICAL RESPIRATOR (KF99) – LEVEL 3	3P Medical Device Pte Ltd	3P03/0001



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DESCRIPTION OF SAMPLE (cont'd)



Figure 1: "SURGICAL RESPIRATOR (KF99) - LEVEL 3" sample as received



Figure 2: "SURGICAL RESPIRATOR (KF99) - LEVEL 3" sample packaging as received

METHOD OF TEST

ASTM F2101-19 Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of *Staphylococcus aureus*.

Area contacting with the bacterial challenge: Inside of the mask

Flowrate: 28.3 ± 0.3 L/min

Mean particle size of the challenge aerosol: $3 \mu m \pm 0.3 \mu m$

Test area: Approximately 50 cm²

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RESULTS

Sample Description: SURGICAL RESPIRATOR (KF99) - LEVEL 3

Test sample/ controls	Stage 1, CFU	Stage 2, CFU	Stage 3, CFU	Stage 4, CFU	Stage 5, CFU	Stage 6, CFU	Sum of Total plate count for the 6 sieves, CFU	Average Count for Controls, CFU	BFE (%)
-ve Control	0	0	0	0	0	0	0		
+ve Control 1	155	399	742	738	490	8	2532	2569	
+ve Control 2	129	413	819	734	501	9	2605		
Sample 1	0	0	0	0	0	0	0		100.00
Sample 2	0	0	0	0 8	0	0	0		100.00
Sample 3	0	0	0	0	1	0	1		99.96
Sample 4	0	0	0	0	0	0	0		100.00
Sample 5	0	0	0	0	1	0	1		99.96

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Notes:

CFU : Colony Forming Unit

BFE : Bacterial Filtration Efficiency

Remarks:

The above test results relate to the samples as received.

MS AW HWEE YING HIGHER TECHNICAL EXECUTIVE MR RANDY CHIN KOK FEI PRODUCT MANAGER MICROBIOLOGY CHEMICAL & MATERIALS

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