Nelson Labs.
A Sotera Health company

Sponsor:
Clara Chan
Action Medical Sundries Limited
RM. 810 8/F VANTA INDUSTRIAL CENTRE
21-33 TAI LIN PAI RD.
KWAI CHUNG, N.T., HONG KO, CN 852
CHINA

Microbial Cleanliness (Bioburden) of Medical Masks Final Report

Test Article: CANUXI Earloop Procedure Mask
Study Number: 1294327-S01
Study Received Date: 29 Apr 2020
Testing Facility: Nelson Laboratories, LLC
6280 S. Redwood Rd.
Salt Lake City, UT 84123 U.S.A.
Test Procedure(s): Standard Test Protocol (STP) Number: STP0036 Rev 15
Customer Specification Sheet (CSS) Number: 202002480 Rev 01
Deviation(s): None

Summary: The testing was conducted in accordance with EN 14683:2019, with the exception of approximate volumes of eluent used when performing the extraction procedure and a temperature range of 30-35°C used for aerobic incubation.

When bioburden results are calculated using a software program, manual calculations may differ slightly due to rounding. The counts determined on products are colony forming units and may not always reflect individual microorganisms. The sponsor performs any statistical analysis and determines the acceptable limits. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Results:

Unit Number	Weight (g)	Aerobic	Fungal	Total Bioburden (CFU/mask)	Total Bioburden (CFU/g)
1	3.0	3	<3	<5.9	<2.0
2	3.2	33	<3	<35.8	<11.2
3	3.1	6	3	8.9	2.9
4	3.1	30	<3	<32.6	<10.5
5	3.2	9	3	11.8	3.7

< = No Organisms Detected
Note: The results are reported as colony forming units per test article.

Method Suitability:

Organism	Percentage
Bacillus atrophaeus	80%

Robert Putnam electronically approved
Study Director Robert Putnam

27 May 2020 14:38 (+00:00)
Study Completion Date and Time

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Study Completion Date and Time

Test Report

No.T32020290541SN Date: Nov 02, 2020

ACTION MEDICAL SUNDRIES LIMITED

ROOM 810, 8/F, VANTA INDUSTRIAL CENTRE, 22-33 TAI LIN PAI ROAD, KWAI CHUNG, N.T.,

HONG KONG

The following samples were submitted and identified by/on behalf of the client as:

CANUXI EARLOOP PROCEDURE MASK

Case No.	:	CA320202922269
Lot No. / Batch Code	:	NOT PROVIDED
Sample Description	:	BLUE MASK
Quantity Submitted	:	10 PCS
Country of Origin	:	HONG KONG
Sample Receiving Date	:	SEP 16, 2020
Testing Period	:	SEP 16, 2020 – NOV 02, 2020

Test Requested	Conclusion
Viral filtration efficiency (VFE) (With reference to ASTM F2101)	See Result

******** FOR FURTHER DETAILS, PLEASE REFER TO THE FOLLOWING PAGE(S) ********

Signed for and on behalf of
SGS Hong Kong Ltd.

Au Kam Chi, Gigi
Technical Manager

Test Results:

Viral filtration efficiency (VFE) With reference to ASTM F2101-19

Test Side	:	White colour (Inside)
Pre-Conditioning	:	Minimum of 4 hours at 21±5°C and 85±5% R.H.
Test Condition	:	21±2 °C and 30-50% R.H.
VFE Test Area	:	~ 40 cm^2
VFE Flow Rate	:	28.3 Litre per minute (L/min)
Mean Particle Size	:	2.8 µm
Positive Control Average	:	1.7 x 10^3 PFU
Negative Monitor Count	:	<1 PFU

Test Specimen	Percent VFE (%)
1	99.8
2	99.6
3	99.0
4	99.8
5	99.9

Note : The test results were conducted by a SGS assessed competent subcontractor laboratory

Sample Photo:

Sample Picture (As received)

SGS authenticate the photo on original report only

*** End of Report ***