

Title:  
 Determination of percentage penetration of 5 micron particle through the textile materials (Group B masks)

QA-L 529

Revision: 01

Page 1 of 5

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NA	01	Rita Eisenberg	Initial release

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**Customer:** Sonovia

**Device:** Face masks

**Document number:** QA 529 [Rev. 01]

Page 2 of 5 pages

## **1. General:**

### **1.1. Testing laboratory:**

TARYAG Labs Ltd.  
14 Ha'llan St.  
Or-Akiva 365101  
Israel.

### **1.2. Sponsor:**

Sonovia  
1 Ha'Bonim St.  
Ramat -Gan

1.3. TARYAG Labs has been accredited by ISRAC for ISO 17025:2017.

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## **2. Objectives:**

- 2.1. The purpose of this report is to summarize the results for determination of percent penetration of 5  $\mu\text{m}$  particles through the textile materials.

## **3. Responsibilities:**

- 3.1. The Testing laboratory is responsible for the following:
  - 3.1.1. Maintain a quality system with compliance to the ISO 17025.
- 3.2. Sponsor responsibilities:
  - 3.2.1. Review of all commissioning qualification documents for release of this protocol.
  - 3.2.2. Review of all operational qualification documents for release of validation.
  - 3.2.3. Verification of conformance with product specifications.

## **4. Standards and regulatory requirements:**

- 4.1. EN 14683:2019 Medical face masks- Requirements and test methods
- 4.2. ASTM F2299/F2299M- Determining the initial efficiency of materials used in medical masks to penetration by particulates using latex spheres

## **5. List of applicable documents:**

- 5.1. WI-L 015 Microbial barrier

## **6. Equipment and Materials**

- 6.1. Microbial barrier system
- 6.2. Polystyrene latex particles (PLS) of 5.0  $\mu\text{m}$
- 6.3. Particle counter
- 6.4. Ultra-pure water

## 7. Test Procedures

### 7.1. General

- 7.1.1. The test was performed based on TARYAG-Labs specific procedures.
- 7.1.2. The parameters of TARYAG-Labs specific procedures may not correlate directly to the parameters required in EN 14683:2019 and ASTM F2299/F2299M standards.

### 7.2. Filtration efficiency (%)

#### 7.2.1. Procedure

- 7.2.1.1. The material was strengthened and was placed into the sample holder (10 X 10 cm).
- 7.2.1.2. Test specimen included all layers of the mask in the order in which they are placed in the complete mask (Table 1); a). Direction that simulating 'exhalation' b). Direction that simulating 'breathing'.
- 7.2.1.3. In order to determine the efficiency of the tested textile materials, polystyrene particles, with a mean size of 5 µm, were delivered through the material and the % penetration was calculated (based on procedure defined in WI-L 015).
- 7.2.1.4. The material creates a filter in the measurement cell and split it into the contaminated side and the clean side. The particles flow direction is from the contaminated to the clean measurement cell side.
- 7.2.1.5. The flow rate of the inlet air was 28 L/min and the pressure differential was 10 Pa.
- 7.2.1.6. Percent (%) penetration of polystyrene particles, with a mean size of 5 µm calculated according to the following formula:

$$\% \text{ Penetration } 5\mu\text{m particles} = \frac{\text{Count of } 5\mu\text{m particles penetrated through the mask}}{\text{Count of } 5\mu\text{m particles used for mask contamination}}$$

- 7.2.1.6 Filtration efficiency (%) results (Tables 1):

	Group B- Masks	
	'Exhalation'	'Breathing'
	2.3	0.5
	1.3	0.8
	0.7	0.7
	0.9	1.1
<b>AVG</b>	1.3	0.8
<b>STDEV</b>	0.7	0.2
<b>MAX</b>	2.3	1.1
<b>MIN</b>	0.7	0.5

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## **11 Documentation and Archiving**

11.3 Original signed protocol will be kept at the sponsor and a copy of original will be kept at TRYAG Labs.

11.4 Validation raw data will be archive at TRYAG Labs in accordance with TARYAG Labs requirements for 7 years.

## **12 Appendixes**

14.1 NA