## **BIOFIL**<sup>TM</sup>

# TECHNICAL DATA SHEET

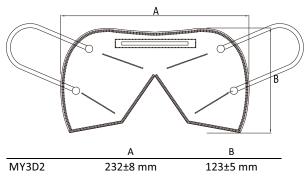
### **Particle Filtering Half Mask**

FFP2 NR Non-Sterile

#### Description

MY3D2: FFP2 NR, Non-sterile, Large size, White, With nose clip

#### Dimensions (Unfolded drawing)



#### **Properties**

Basis weight of non-woven fabrics (first layers): 48 g/m<sup>2</sup>
Basis weight of Hot air cotton (second layers): 45 g/m<sup>2</sup>
Basis weight of Nano fabrics (third layers): 40 g/m<sup>2</sup>
Basis weight of non-woven fabrics (fouth layers): 25 g/m<sup>2</sup>
Particle Filtering Half Mask as defined by EN 149:2001+A1:2009.
Test results as per EN 149:2001+A1:2009 available upon request.

#### Indication

The mask can filter the particles in the air, and block the droplets, blood, body fluids and secretions. It is safe and reliable. Single use product.

#### **Counter indication**

None in particular.

#### Main materials

Mask body: Made of non-woven fabrics (inner and outer layers), Hot air cotton(middle layers) and Nano fabrics (middle layers). Nose clip: Polyethylene + Zinc wire Ear loop: Spandex + Nylon

#### Sterilization

Products are not sterilized.



#### **Packaging**

MY3D2: 10/PK, 1000/carton

#### **Manufacturing**

Products are manufactured in China.

Products are manufactured in a class 100,000 room environment.

The quality system of the manufacturing sites is ISO 13485 Compliant.

#### Regulatory information

Name of regulatory authority: SGS FIMKO OY, Notified Body 0598. Product marketing licence number, Module B: Certificate FI20/965826, Module C2: Certificate CN20/42066.

#### **Storage**

Store the product in a clean room with a relative humidity of less than 80% at room temperature, no corrosive gases, cool, dry, and well ventilated.

#### **Shelf life**

3 years after month of production.

Drawn	Approved
Date	Date
23 Apr 2020	23 <b>Apr</b> 2020
Name	Name
Alex Fang	James