



**Bastos Viegas**

4560-164 Guilhufe, Penafiel - Portugal

Ref: **465-102**

**Technical Specifications**

Brand:



**Description:** Particle filtering half mask

<b>Composition:</b>	Polymer, Polypropylene nonwoven, SB polypropylene nonwoven.
<b>Size variation:</b>	±10 %
<b>Latex:</b>	Free
<b>PVC:</b>	Free
<b>Re use:</b>	No
<b>Sterilizable by:</b>	Ethylene Oxide
<b>PPE Classification(EN 149)</b>	FFP2 NR
<b>Colour:</b>	white
<b>Valve presence:</b>	no
<b>Shelf life:</b>	60 months
<b>CFU/g</b>	<10 <sup>2</sup>
<b>Do not sterilize by</b>	Moist heat
<b>Fluorescence</b>	conform
<b>Filter efficiency</b>	>94
<b>Total inward leakage (TIL)</b>	<8 %
<b>Penetration of filter</b>	<6 %
<b>Breath. Resist.Exhalation</b>	<3 mbar
<b>Breathing Resist.Inhalation</b>	<2,4 mbar

<b>Nr and Revision Date:</b>	17 -- 2019/10/04
<b>CE mark:</b>	CE0194

<b>Directive:</b>	<b>PPE REGULATION (EU) 2016/425</b>
<b>Applicable norms:</b>	EN ISO 11737-1:2006 ; EN149:2001+A1:2009 ; ENISO11737-1:2006/AC:2009 ;

<b>Important Notes:</b>	Outer layer: Spunbond NW +filter:NW /Inner layer:Spunbond NW
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<b>PACKING</b>		With Instructions for use			
Level	Units	Type	Dimension	Stamp	Labels
1	1	Cellophane			
2	20	Folding box			labeled
3	240	Carton box	580 x 382 x 205	stamped	labeled

<b>Important Notes:</b>	PPE category III under EC Type Exa. Cert
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<b>Storage instructions</b>	Store in a dry place at room temperature and protect from sunlight. The product has a good stability and therefore, normal conditions of medical devices storage shall apply
<b>Waste instructions</b>	No special requirements. The waste must be disposed according to local legal regulations for the disposable of medical waste.
<b>Intended use</b>	Intended for user protection as Personal Protective Equipment against particules

<b>WASTE AND ENVIRONMENT REGULATIONS</b>	Weight (gr) of packing material used in 100 pcs	589
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**ISSUED BY: Quality Management Department, 2020/02/26**

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# EU DECLARATION OF CONFORMITY

According to Annex IX Personal Protective Equipment Regulation (EU) 2016/425

## 1. Personal protective equipment:

Particle filtering half mask	
465-100	FFP1 NR, non valved
465-101	FFP1 NR, valved
465-102	FFP2 NR, non valved
465-103	FFP2 NR, valved
465-104	FFP3 NR, valved

## 2. Manufacturer:

BASTOS VIEGAS S.A  
Avenida da Fábrica nº298, 4560-164 Guilhufe, Penafiel, Portugal  
Tel: +351 255 729 500-Fax: +351 255 729 501-Email: geral@bastosviegas.com-www.bastosviegas.com

## 3. This declaration of conformity is issued under the sole responsibility of the manufacturer

## 4. Object of the declaration

Particle filtering half mask  
Personal Protective Equipment Category III

## 5. The object of the declaration is in conformity with the relevant Union harmonisation legislation

Personal Protective Equipment Regulation (EU) 2016/425

## 6. References to the relevant harmonised standards used or references to the other technical specifications in relation to which conformity is declared:

EN 149:2001+A1:2009

## 7. The notified body performed the EU type-examination (Module B) and issued the EU type-examination certificate.

Notified body: INSPEC International Ltd.  
Number : 0194  
56 Leslie Hough Way, Salford, Greater Manchester M6 6AJ, United Kingdom

EU type-examination certificate: PPE18161071

## 8. The PPE is subject to the conformity assessment procedure under surveillance of the notified body.

Notified body: INSPEC International Ltd.  
Number : 0194  
56 Leslie Hough Way, Salford, Greater Manchester M6 6AJ, England

Conformity Assessment: According with Module C2 (Annex VII) of Personal Protective Equipment (EU) 2016/425


## 9. Additional information

The fulfilment of the applicable Essential Health and Safety Requirements have been demonstrated according to Annex II of PPE (EU) 2016/425.

Signed for and on behalf of Bastos Viegas S.A.:

Penafiel, 03/10/2019

  
Regulatory affairs  
Fátima Sá Couto

  
Managing Director  
Luís Guimarães



PPE\_EU REG EU DEC OF CONFORMITY REV01

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