

# PRODUCT SPECIFICATION

Product PN **TA224BHP3G030B00**

Mod. 984

Description **BACTERIAL AIR VENTS WITH CAP 3µm – White**

Rev. 02

## Bacterial Air Vent With Cap 3µm



<b>PRODUCT DESCRIPTION</b>	<p>Bacterial Air Vent white Is a non-sterile vent with hydrophobic membrane (Ac-Ny 3,0 µm) The product is provided in bulk packs for further manufacturing.</p>
<b>MATERIALS</b>	<p><b>Membrane:</b> Fortex - PVDF Hydrophobic Hemorepellent - Pore Size: 3,0 µm <b>Housing:</b> Polypropylene and white colorant</p>
<b>PRODUCT CHARACTERISTIC</b>	<p><b>FOR RAW MATERIALS USED TO PRODUCE COMPONENT</b> based on the available documentation from raw materials suppliers:</p> <p><u>MEMBRANE</u></p> <ul style="list-style-type: none"> <li><input checked="" type="checkbox"/> Test performed in compliance with USP class VI and/or ISO 10993-1.</li> <li><input checked="" type="checkbox"/> DEHP free</li> <li><input checked="" type="checkbox"/> Latex free</li> <li><input checked="" type="checkbox"/> BPA free</li> <li><input checked="" type="checkbox"/> BSE/TSE free</li> <li><input checked="" type="checkbox"/> all materials are in compliance with RoHS Directive 2011/65/EU and REACH regulation 1907/2006/EC</li> <li><input checked="" type="checkbox"/> REACH regulation 1907/2006/EC</li> </ul> <p><u>HOUSING granule</u></p> <ul style="list-style-type: none"> <li><input checked="" type="checkbox"/> Test performed in compliance with USP class VI and/or ISO 10993-1.</li> <li><input checked="" type="checkbox"/> Europe - BSE/TSE - "Mad Cow": Tallow derived materials used in this product fulfill the requirements laid down in the Regulations 1069/2009/EC, and 142/2011/EC, and the "Note for Guidance EMEA/410/01, rev. 3".</li> <li><input checked="" type="checkbox"/> DEHP product may contain chemical substances at very low levels (less than 10 ppm)</li> <li><input checked="" type="checkbox"/> Latex free</li> <li><input checked="" type="checkbox"/> BSE/TSE free</li> <li><input checked="" type="checkbox"/> Conform to Restriction of Hazardous Substances in Electric and Electronic Equipment (RoHS)</li> <li><input checked="" type="checkbox"/> Bisphenol A; (BPA) Free</li> <li><input checked="" type="checkbox"/> Conform to REACH regulation 1907/2006/EC</li> </ul> <p><u>HOUSING granule colorant</u></p> <ul style="list-style-type: none"> <li><input checked="" type="checkbox"/> Food contact: ( in order receive information on a specific regulation, forward the request to GVS).</li> </ul> <p>raw material complies with European Union raw material complies EU National Legislations the composition of this product complies with many National Legislations, Recommendations Communications for the production of food packaging The base resin in this product meets the FDA requirements contained in the Code of Federal Regulations in 21 CFR 177.1520(a)(3)(i) and (c)3.2a.</p> <ul style="list-style-type: none"> <li><input checked="" type="checkbox"/> BPA free</li> </ul>

# PRODUCT SPECIFICATION

<b>Product PN</b>	<b>TA224BHP3G030B00</b>	<b>Mod. 984</b>
<b>Description</b>	<b>BACTERIAL AIR VENTS WITH CAP 3µm – White</b>	<b>Rev. 02</b>

	<input checked="" type="checkbox"/> Latex free <input checked="" type="checkbox"/> Conform to REACH regulation 1907/2006/EC <input checked="" type="checkbox"/> Conform to Restriction of Hazardous Substances in Electric and Electronic Equipment (RoHS):  <p>Note: Despite above reported, the manufacturer of a medical device made with this product must still evaluate the medical device to show that it fully meets the requirements of the applicable sections of ISO 10993.</p>
<b>STERILIZATION</b>	<input type="checkbox"/> Not required; <input checked="" type="checkbox"/> EtO; <input checked="" type="checkbox"/> Gamma; <input type="checkbox"/> Beta; Steam; <input type="checkbox"/> e-beam
<b>PACKAGING AND LABELLING</b>	<p>50.000 pcs packed in two PE bags. Bags are separately closed.            The first bar-code label is between the 2 bags.            The second bar-code label is stuck outside the box.</p> <p>Each bag is labeled with the following traceability information:</p> <ul style="list-style-type: none"> <li>- Quantity</li> <li>- Product description</li> <li>- Product date</li> <li>- Lot number (OL and digit batch number to trace back to raw materials used)</li> <li>- Operator code</li> </ul> <p>Different lot of goods in one shipment are packed in a manner to prevent mix-ups.            Different lots in one box are separately closed and separately labeled to prevent mix-ups.</p>
<b>CERTIFICATE OF COMPLIANCE</b>	<p>Conformity declaration is printed on every invoice and Certificate is according to UNI EN 10204 type 2.1            The Quality management system is in compliance with ISO 9001, ISO 13485.</p>

Product PN **TA224BHP3G030B00**

Mod. 984

Description **BACTERIAL AIR VENTS WITH CAP 3µm – White**

Rev. 02

## VISUAL REQUIREMENTS

*Visual acceptance requirements apply when inspected under below conditions:*

**Instrument inspection** with naked eye and light source

**Distance** of 300-450 mm.

**Timings:** 5 sec per unit

Acceptance Requirement		AQL	Sampling Plan
1	Incomplete plastic support	0.1	ISO 2859 part. 1 1 <sup>st</sup> Level
2	Deformation of plastic support, shrinkages of material	0.1	
3	Incomplete, misplaced, missing membrane	0.1	
4	Double or partially double membrane	0.1	
5	Membrane broken, pierced, crushed	0.1	
6	Infiltration > 50% of material membrane surface	0.1	
7	Part with broken or missing cap	0.1	
8	Membrane incorporated residual	0.1	
9	Internal cap deformation (bubble)	0.1	
10	Flashes > 0,4 mm	1	
11	Infiltration < 50% of the membrane surface	1	
12	Jutting membrane threads	1	
13	Embedded particulate matter > 0,1 mm <sup>2</sup>	1.5	
14	Color not uniform	1.5	
15	Marks or scratches	1.5	
16	Incompleteness's not compromising the functionality of the part	1.5	
17	Slight mould, rust dirty	1.5	
18	Loose particulate matter > 0,1 mm <sup>2</sup>	1.5	
19	Mould dirty <20% of material surface (GVS does not accept complaint due to mold dirty with percentage ≤ 10%)		>10%

\* Embedded Particulate Matter: according to Dirt Estimation Chart (Tappi Standard).

## PERFORMANCE REQUIREMENTS

Acceptance Requirement		AQL	Sampling Plan
1	Air flow	Pressure 25 cm/H <sub>2</sub> O ≥ 80 ml/min	ISO 2859 part. 1 – S3 Special inspection level, single sampling plan, normal inspection
2	WBT	Pressure 800mm/H <sub>2</sub> O for 5 min	
3	Air CAP tightness	0,6 Bar for 1 min	
4	Dimensional assembling diameter	internal diameter 4.26 +/- 0.03 mm Gauge go/ no go	ISO 2859 part. 1 – S3 Special inspection level, single sampling plan, normal inspection
5	Dimensional assembling diameter	external diameter 6.33 +/- 0.03 mm Gauge go/ no go	



**Note:** WBT test method, ramped pressure from 0 to 800mm/H<sub>2</sub>O in 10 seconds.

# PRODUCT SPECIFICATION

Product PN	<b>TA224BHP3G030B00</b>	Mod. 984
Description	BACTERIAL AIR VENTS WITH CAP 3µm – White	Rev. 02

This material specification describes the properties of product above indicated.  
This document contains general requirements, material description, drawing references, defect specification, biological material requirements.

## REVISIONS AND APPROVALS:

DATE	REV.	REASON FOR CHANGE	ISSUED AND CONTROLLED BY: (name /function and signature)	APPROVED BY: (name /function and signature)
22/06/2017	00	First issue	Domenico Romondia Project Manager 	Isabella Frignani Process Quality Assurance 

## Customer Approval:

We accept this material specification as a part of the agreed terms of delivery

Company name \_\_\_\_\_

Approved by: \_\_\_\_\_  
(Name, Function) (Signature)

Date \_\_\_\_\_  
(Company stamp)

Please send back this document signed for approval. If we will not receive this specification signed , we consider the first order placed as implicit approval.