



PRODUCT SPECIFICATION

Product PN	TA224BHP3G030V00	Mod. 984
Description	BACTERIAL AIR VENTS WITH CAP	Rev. 00

Bacterial Air Vent With Cap



PART DESCRIPTION	<p>Bacterial Air Vent</p> <p>Is a non-sterile vent with hydrophobic membrane (Ac-Ny 3,0µm)</p> <p>The product is provided in bulk packs for further manufacturing.</p>
MATERIALS	<p>Membrane: Fortex - PVDF Hydrophobic Memorepellent - Pore Size:3,0µm</p> <p>Housing: Polypropylene and colorant</p>
PRODUCT CHARACTERISTICS	<p>Weight : 0,5gr</p> <p>Total Height: 9,95mm with closed cap</p>
STERILIZATION	Ethylene oxide – Gamma (25 kGy)
BIOLOGICAL REQUIREMENTS	<p>FOR RAW MATERIALS USED TO PRODUCE COMPONENT</p> <p>based on the available documentation from raw materials suppliers:</p> <p><u>MEMBRANE</u></p> <ul style="list-style-type: none">-Test performed in compliance with USP class VI and/or ISO 10993-1.-DEHP free-Latex free-BPA free-BSE/TSE free-all materials are in compliance with RoHS Directive 2011/65/EU and REACH regulation 1907/2006/EC <p><u>HOUSING granule</u></p> <ul style="list-style-type: none">-Test performed in compliance with USP class VI and/or ISO 10993-1.-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".-DEHP product may contain chemical substances at very low levels (less than 10 ppm)-Latex free-BSE/TSE free-Restriction of Hazardous Substances in Electric and Electronic Equipment (RoHS): Regulation refers to electrical and electronic equipment and not specifically to plastic raw materials. However, based on the available documentation from raw materials suppliers, this granule complies with the requirements of the Directives 2002/95/EC, as amended, and 2011/65/EU concerning the limits of cadmium, lead, mercury, hexavalent chromium, polybrominated biphenyls (PBB) and polybrominated diphenyl ethers (PBDE).- Bisphenol A; (BPA) Free <p><u>HOUSING granule colorant</u></p> <ul style="list-style-type: none">-Food contact: (in order receive information on a specific regulation, forward the request to GVS). <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">-BPA free <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>



PRODUCT SPECIFICATION

Product PN

TA224BHP3G030V00

Mod. 984

Description

BACTERIAL AIR VENTS WITH CAP

Rev. 00

PACKAGING AND LABELLING

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.

Each bag is labeled with the following traceability information:

- Quantity
- Product description
- Product date
- Lot number (OL and digit batch number to trace back to raw materials used)
- Operator code

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.

CERTIFICATE OF COMPLIANCE

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.

DRAWING

The attached drawing is part of this material specification and must not be duplicated or made accessible to a third party without prior written GVS SpA consent.

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	
1	1. Incomplete plastic support 2. Deformation of plastic support, shrinkages of material 3. Incomplete, misplaced, missing membrane 4. Double or partially double membrane. 5. Membrane broken, pierced, crushed 6. Infiltration > 50% of material membrane surface 7. Part with broken or missing cap 8. Membrane incorporated residual 9. Internal cap deformation (bubble) 10. Serious mould, rust dirty	0,1	ISO 2859 part. 1 1 st Level
2	11. Flashes > 0,4 mm 12. Infiltration < 50% of the membrane surface 13. Jutting membrane threads	1	
3	14. *Embedded particulate matter > 0,1 mm ² 15. Color not uniform 16. Marks or scratches 17. Incompleteness's not compromising the functionality of the part 18. Slight mould, rust dirty. 19. Loose particulate matter > 0,1 mm ²	1,5	

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



PRODUCT SPECIFICATION

Product PN **TA224BHP3G030V00**

Mod. 984

Description **BACTERIAL AIR VENTS WITH CAP**

Rev. 00

PERFORMANCE REQUIREMENTS



Air flow	WBT	Air CAP tightness	AQL
Pressure 25 cm/H ₂ O ≥ 80 ml/min	Pressure 800mm/H ₂ O for 5 min	0,6 Bar for 1 min	AQL 0,1 ISO 2859 part. 1 1st Level

Note: WBT test method, ramped pressure from 0 to 800mm/H₂O in 10 seconds.

Acceptance Requirement			AQL	Sampling Plan
1	Dimensional assembling diameter	internal diameter	0,1	ISO 2859 part. 1 1 st Level
1	Dimensional assembling diameter	external diameter	0,1	

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

REVISIONI / REVISIONS:

DATA /DATE	REV.	MODIFICA DA PRECEDENTE REVISIONE/ REASON FOR CHANGE	MODIFICATO DA / CHANGED BY (name /function and signature)	APPROVATO DA/APPROVED BY (name /function and signature)
12/06/2014	00	First issue	Isabella Frignani Process Quality Assurance 	Isabella Frignani Process Quality Assurance 

Customer Approval:

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

Date _____ Signature _____

(Company, Name, Function, Signature)

(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.