

PRODUCT SPECIFICATION

Product PN	TA224BHP3G030B00 TA224BHP3G030V00	☐ PRELIMINARY ☐ R&D RELEASED ☒ RELEASED	Mod. 984c Rev. 05
Description	BACTERIAL AIR VENTS WITH CAP		

Bacterial Air Vent With Cap



PRODUCT DESCRIPTION	Bacterial Air Vent It is a non-sterile vent with hydrophobic membrane. The product is provided in bulk packs for further manufacturing.			
MATERIALS	Part number	Membrane	Frame/Housing	Color
	TA224BHP3G030B00	Haemophobic/hydrophobic membrane 3.0 µm PVDF	Polypropylene (PP)	Masterbatch White
	TA224BHP3G030V00			Masterbatch Blue
PRODUCT CHARACTERISTIC	FOR RAW MATERIALS USED TO PRODUCE COMPONENT based on the available documentation from raw materials suppliers: <u>MEMBRANE</u> ☒ 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 ☒ REACH regulation 1907/2006/EC <u>HOUSING granule</u> ☒ 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 ☒ Conform to Restriction of Hazardous Substances in Electric and Electronic Equipment (RoHS) ☒ Bisphenol A; (BPA) Free ☒ Conform to REACH regulation 1907/2006/EC <u>HOUSING granule colorant</u> ☒ Food contact: (in order receive information on a specific regulation, forward the request to GVS). 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. ☒ BPA free ☒ Latex free ☒ Conform to REACH regulation 1907/2006/EC ☒ Conform to Restriction of Hazardous Substances in Electric and Electronic Equipment (RoHS): 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.			

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PRODUCT SHELF LIFE	5 years at indoor storage condition, without direct exposure to the elements (sunlight, etc.) from the date reported on the barcode label.
STERILIZATION	STERILE: ☐ Yes ☒ No SUITABLE FOR STERILIZATION: ☒ Yes ☐ No ☒ EtO; ☒ Gamma; ☐ Beta; ☐ Steam; ☐ e-beam
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	With each shipment, GVS SpA Customer Service will send the CoC to the Customer, based on the lot numbers and date of manufacture. 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 9001:2015.
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.
ACCEPTABLE QUALITY LEVEL	☒ AQL: with sampling Plan ☐ PPM: smaller than ☐ Other:

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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 st 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	Oil, grease, rust dirty, burn mark	0.1	
11	Jutting injection gate > 0.2 mm	1	
12	Flashes > 0,4 mm	1	
13	Infiltration < 50% of the membrane surface	1	
14	Jutting membrane threads	1	
15	Embedded particulate matter > 0,1 mm ²	1.5	
16	Color not uniform	1.5	
17	Marks or scratches	1.5	
18	Incompleteness's not compromising the functionality of the part	1.5	
19	Slight mould, rust dirty	1.5	
20	Loose particulate matter > 0,1 mm ²	1.5	

Only
for

TA224BHP3G030V00:

21	Mould dirty <20% of material surface (GVS does not accept complaint due to mold dirty with percentage ≤ 10%)	>10%
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* Embedded Particulate Matter: according to Dirt Estimation Chart (Tappi Standard).

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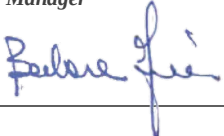
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PERFORMANCE REQUIREMENTS	Acceptance Requirement			AQL	Sampling Plan
	1	Air Flow	Pressure 25 mbar ≥ 80 ml/min	0.1	ISO 2859 part. 1 – S3 Special inspection level, single sampling plan for normal inspection
	2	WBT	Pressure 0.08bar for 5 min	0.1	
	3	Air CAP Tightness	0,6 Bar for 1 min	0.1	
	4	Dimensional assembling diameter	Internal diameter 4.26 +/- 0.03 mm Gauge go/ no go	0.1	
	5	Dimensional assembling diameter	External diameter 6.33 +/- 0.03 mm Gauge go/ no go	0.1	
Note: WBT test method, ramped pressure from 0 to 0.08 bar in 10 seconds.					

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)
12/06/2014	00	First issue	Isabella Frignani Process Quality Assurance	Isabella Frignani Process Quality Assurance
13/06/2024	01	Update to new format. Corrected membrane description from Ac- Ny 3.0µm to PVDF 3.0µm. Deleted compliance to ISO 13485. Unified TA224BHP3G030B00 and TA224BHP3G030V00 TDS	Silvio Tosi Product&Process Quality Assurance	Barbara Finessi Quality Manager Nicola Bassani Sales Director EMEA
21/08/2026	02	Fixed an error correction, added lines 10 and 11 to the visual requirements table, and converted the functional test pressures to bar	Sara Greco Product&Process Quality Assurance 	Barbara Finessi Quality Manager 

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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.