

PRODUCT SPECIFICATION

Product PN TA160AEPTG030B00-TA160AEPTG030D00-TA160AEPTG012B00	<input type="checkbox"/> PRELIMINARY <input type="checkbox"/> R&D RELEASED <input checked="" type="checkbox"/> RELEASED	Mod. 984c
Description Bacterial Air Vents with closing cap and hydrophobic membrane		Rev. 05

Bacterial Air Vents With closing cap and hydrophobic membrane



PRODUCT DESCRIPTION	Bacterial air vent with hydrophobic membrane as filter material and closing cap in different pore size 3,0 µm or 1,2 µm and colors, blue or white. The product is provided in bulk packs for further assembling.																											
INTENDED USE / APPLICATION	IV sets and other devices requiring vents to maintain a balance between internal and ambient pressures together with a protection against bacterial or fungi contamination during usage.																											
MATERIALS	<table><tr><th>Part No.</th><th>Item:</th><th>Material:</th><th>Color:</th></tr><tr><td rowspan="2">TA160AEPTG030B00</td><td>Housing</td><td>Polypropylene (PP) + masterbatch</td><td>White</td></tr><tr><td>Filter material</td><td>3,0 µm pore size membrane hydrophobic PVDF/PET</td><td>White</td></tr><tr><td rowspan="2">TA160AEPTG030D00</td><td>Housing</td><td>Polypropylene (PP) + masterbatch</td><td>Blue</td></tr><tr><td>Filter material</td><td>3,0 µm pore size membrane hydrophobic PVDF/PET</td><td>White</td></tr><tr><td rowspan="2">TA160AEPTG012B00</td><td>Housing</td><td>Polypropylene (PP) + masterbatch</td><td>White</td></tr><tr><td>Filter material</td><td>1,2 µm pore size membrane hydrophobic PVDF/PET</td><td>White</td></tr></table> <p>For raw materials used to produce components, Regulatory Documentation Required: <u>raw material membrane:</u> Test performed in compliance with USP class VI and/or ISO 10993-1.</p> <p><u>raw material membrane and granule:</u> Regulatory Documentation Required: <input checked="" type="checkbox"/> Rohs, directive 2002/95/CE <input checked="" type="checkbox"/> BSE/TSE, directive 2003/32/CE <input checked="" type="checkbox"/> DEHP plasticizer Free and latex free <input checked="" type="checkbox"/> Reach 1907/2006/CE (hazardous substances regulation) <input checked="" type="checkbox"/> Conflict minerals</p>			Part No.	Item:	Material:	Color:	TA160AEPTG030B00	Housing	Polypropylene (PP) + masterbatch	White	Filter material	3,0 µm pore size membrane hydrophobic PVDF/PET	White	TA160AEPTG030D00	Housing	Polypropylene (PP) + masterbatch	Blue	Filter material	3,0 µm pore size membrane hydrophobic PVDF/PET	White	TA160AEPTG012B00	Housing	Polypropylene (PP) + masterbatch	White	Filter material	1,2 µm pore size membrane hydrophobic PVDF/PET	White
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Mod. 984c

Description Bacterial Air Vents with closing cap and hydrophobic membrane

Rev. 05

PRODUCT CHARACTERISTICS

Dimensions:

Total height	11,25 mm
Total width	10,60 mm
Outside diameter (assembling side)	6,27 mm
Internal diameter (assembling side)	4,00 mm

STERILIZATION

☒ EtO;

For other sterilization process please contact the sales representative of your country

PRODUCT SHELF LIFE

5 years

PACKAGING AND LABELLING

One box of 50.000 pcs divided in two PE bags of 25.000 pcs (one external bag 60x25-25x90 that contains two bags with 25.000 pcs closed separately). The bar-code labels are stuck on the bags and outside the carton.

Each bag is labeled with the following traceability information:

Quantity

Product description

Product date

Lot number (OL and 6 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 carton 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 S.p.A. consent

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VISUAL REQUIREMENTS

Visual acceptance requirements apply when inspected under below conditions:
 Magnification: None
 Light type: naked eye + lamp
 Timing: 5 sec per unit
 Distance: 30-45 cm

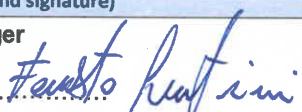
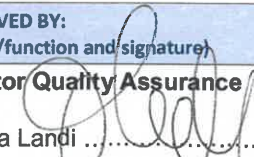
Acceptance Requirement		AQL	Sampling Plan
1	Plastic support incomplete	0,1	ISO 2859 part. 1 1 st Level inspection, normal inspection.
2	Deformations/squeezed parts	0,1	
3	Porosities, shrinkages	0,1	
4	Partially or totally missing membrane	0,1	
5	Membrane double	0,1	
6	Membrane broken	0,1	
7	Membrane crushed	0,1	
8	Plastic infiltration > 0,2 mm of the filter surface	0,1	
9	Membrane residual on the part	0,1	
10	Bubbles	0,1	
12	Flashes > 0,4 mm	1	
13	Jutting injection gate > 0,2 mm	1	
14	Threads	1,5	
15	Plastic infiltration < 0,2 mm of the filter surface	1,5	
16	*Embedded particulate matter > 0,1 mm ²	1,5	
17	Not uniform coloring/streaks	1,5	
18	Scrapes	1,5	
19	Dirty, grease or rust on the part	1,5	
20	*Loose contamination > 0,1 mm ²	1,5	

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DIMENSIONAL REQUIREMENTS							
	Acceptance Requirement		Value of reference		AQL	Sampling Plan	
	1	Internal diameter	MIN = 3,95 mm MAX = 4,05 mm		0,1	ISO 2859 part. 1 S3 Special inspection level	
2	External diameter	MIN = 6,22 mm MAX = 6,32 mm					
PERFORMANCE REQUIREMENTS							
	Filter PN		Air flow	*WBT	Tightness of the cap	AQL	Sampling Plan
	1	TA160AEPTG030B00	≥30 scc/min Pressure 15 mbar (15cmH ₂ O)	0.08bar for 2 min	0,3 bar for 15 sec. no bubbles accepted	0,1	ISO 2859 part. 1 S3 Special inspection level
	2	TA160AEPTG030D00					
	3	TA160AEPTG012B00	≥15 scc/min Pressure 15 mbar (15cmH ₂ O)	0.16 bar for 2 min			
*Note: WBT test method, ramped pressure from 0 to 0.08 / 0.16bar 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)
18/03/2021	00	First issue	Project Manager Fausto Lentini..... 	Director Quality Assurance Tiziana Landi 

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.