

PRODUCT SPECIFICATION

Product PN	TA156ATEKG002B00	<input type="checkbox"/> PRELIMINARY <input type="checkbox"/> R&D RELEASED <input checked="" type="checkbox"/> RELEASED	Mod. 984c Rev. 05
Description	Bacterial Air Vent made whit 0.2 µm PVDF/PET Hydrophobic Membrane		

Bacterial Air Vent



PRODUCT DESCRIPTION	Bacterial Air Vent made whit 0.2µm PVDF/PET Hydrophobic Membrane. Non-sterile vent. The product is provided in bulk packs for further manufacturing.											
INTENDED USE / APPLICATION	Air Vent for infusion set											
MATERIALS	<table><tr><th>P/N</th><th>Housing material</th><th>Filter media</th><th>COLOR</th></tr><tr><td>TA156ATEKG002B00</td><td>ABS</td><td>0.2 µm pore size membrane hydrophobic PVDF/PET</td><td>White</td></tr></table>				P/N	Housing material	Filter media	COLOR	TA156ATEKG002B00	ABS	0.2 µm pore size membrane hydrophobic PVDF/PET	White
	P/N	Housing material	Filter media	COLOR								
TA156ATEKG002B00	ABS	0.2 µm pore size membrane hydrophobic PVDF/PET	White									
	<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. <u>raw material granule:</u></p> <p>Regulatory Documentation Required:</p> <ul style="list-style-type: none"><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"/> Latex free<input checked="" type="checkbox"/> Conflict minerals<input checked="" type="checkbox"/> BPA and phthalates Free											

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PRODUCT CHARACTERISTICS

Dimensions:

Total height	11,70 mm
Total width	9,80 mm
Outside diameter (assembling side)	8,20 mm
Internal diameter (assembling side)	6,33 mm

STERILIZATION

SUITABLE FOR STERILIZATION : : ☒ Yes ☐ No

☒ EtO;
☒ Gamma (Max 25kGy);

PRODUCT SHELF LIFE

5 years

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 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 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 – S3 Special inspection level.
2	Deformations/squeezed parts	0,1	
3	Porosities, shrinkages	0,1	
4	Partially or totally missing membrane	0,1	
5	Double membrane	0,1	
6	Broken membrane	0,1	
7	Squeezed membrane	0,1	
8	Plastic infiltration > 0.2mm of the filter surface	0,1	
9	Membrane residual on the part	0,1	
10	Bubbles	0,1	
11	Dirty, grease on the part	0,1	
12	Rust on the part	0,1	
13	Flashes > 0,4 mm	1	
14	Plastic infiltration ≤ 0.2mm of the filter surface	1	
15	Threads	1	
16	Jutting injection gate > 0,2 mm	1	
17	*Embedded particulate matter > 0,1 mm ²	1,5	
18	Not uniform coloring/streaks	1,5	
19	Scrapes	1,5	
20	Embedded or loosing dirt not compromising the functionality of the part	1,5	
21	Loose contamination > 0,1 mm ²	1,5	

DIMENSIONAL REQUIREMENTS

Acceptance Requirement	Value of reference	AQL	Sampling Plan
Internal diameter	6,33±0.05mm gauge go/no go	0,1	ISO 2859 part. 1 – S3 Special inspection level.

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PERFORMANCE REQUIREMENTS				
	Functional Testing		AQL	Sampling Plan
	Air flow	≥ 4 scc/min (Pressure 98 mbar)	0,1	ISO 2859 part. 1 1 st Level inspection
	Water Break Through	WBT ≥ 0.08bar for 2 min	1	

***Note:** WBT test method, ramped pressure from 0 to 0.08bar 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.