

# PRODUCT SPECIFICATION

Product PN	TA156AFLEG002B00 TA156BFLEG002B00	<input type="checkbox"/> PRELIMINARY <input type="checkbox"/> R&D RELEASED	Mod. 984c
Description	Bacterial Air Vent made whit 0.2 µm PVDF/PET Haemophobic/Hydrophobic Membrane	<input checked="" type="checkbox"/> RELEASED	Rev. 05

## Bacterial Air Vent



PRODUCT DESCRIPTION	Detailed description of the product: *Bacterial Air Vent made whit 0.2µm PVDF/PET Haemophobic/Hydrophobic Membrane												
INTENDED USE / APPLICATION	Describe 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>TA156AFLEG002B00</td><td rowspan="2">Polyethylene</td><td rowspan="2">0.2 µm pore size PVDF/PET Haemophobic/ hydrophobic membrane</td><td rowspan="2">White</td></tr><tr><td>TA156BFLEG002B00</td></tr></table>				P/N	Housing material	Filter media	COLOR	TA156AFLEG002B00	Polyethylene	0.2 µm pore size PVDF/PET Haemophobic/ hydrophobic membrane	White	TA156BFLEG002B00
	P/N	Housing material	Filter media	COLOR									
	TA156AFLEG002B00	Polyethylene	0.2 µm pore size PVDF/PET Haemophobic/ hydrophobic membrane	White									
	TA156BFLEG002B00												
	<b>For raw materials used to produce components, Regulatory Documentation Required:</b>												
<u>raw material membrane:</u> Test performed in compliance with USP class VI and/or ISO 10993-1.													
raw material membrane and granule: <u>Food contact</u> European Pharmacopoeia1.3. "Polyolefines"(5th edition - 2005) USA USP 28 "POLYETHYLENE CONTAINERS"													
<b>Regulatory Documentation Required:</b> <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 <input checked="" type="checkbox"/> Latex free <input checked="" type="checkbox"/> BPA and phthalates Free													

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PRODUCT CHARACTERISTICS	Dimensions:	
	Total height	11,60 mm
	Total width	9,70 mm
	Outside diameter (assembling side)	8,10 mm
	Internal diameter (assembling side)	6,27 mm
STERILIZATION	<input checked="" type="checkbox"/> EtO; <input checked="" type="checkbox"/> Gamma (Max 25kGy);	
PRODUCT SHELF LIFE	5 years	
PACKAGING AND LABELLING	<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:            Quantity            Product description            Product date            Lot number (OL and batch number to trace back to raw materials used)            Operator code</p> <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>	
CERTIFICATE OF COMPLIANCE	<p>Conformity declaration is printed on every invoice and Certificate is according to UNI EN 10204 type 2.1</p> <p>The Quality management system is in compliance with ISO 9001, ISO 13485.</p>	
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 <sup>st</sup> Level inspection, single sampling plan, 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 > 0,2mm of membrane 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 > 0,2mm of membrane surface	1,5	
16	*Embedded particulate matter > 0,1 mm <sup>2</sup>	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 <sup>2</sup>	1,5	

The characteristics above listed are statistically inspected during the manufacturing process.

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



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DIMENSIONAL REQUIREMENTS					
	Acceptance Requirement		Value of reference	AQL	Sampling Plan
	1	Internal diameter	6,27±0.05mm gauge go/no go	0,1	Sampling plan according to ISO 2859 part. 1 – S3 Special inspection level, single sampling plan, normal inspection
PERFORMANCE REQUIREMENTS					
	Functional Testing		AQL	Sampling Plan	
	Air flow	≥ 14 cc/min (Pressure 98 mbar)	0,1	Sampling plan according to ISO 2859 part. 1 – S3 Special inspection level, single sampling plan, normal inspection	
	Water Break Through	0,5 bar x 2min	0,1		
<b>*Note:</b> WBT test method, ramped pressure from 0 to 0,5 bar in 20 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)
26/10/2021	00	First issue	Project Manager Marco Piazzì	Director Quality Assurance GVS Sud Roberta Frulla

## 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.