

PRODUCT SPECIFICATION

Product PN	TA156AFLEG012B00 TA156BFLEG012B00	<input type="checkbox"/> PRELIMINARY	Mod. 984c Rev. 05
		<input checked="" type="checkbox"/> R&D RELEASED	
Description	Bacterial Air Vent made with 1.2µm PVDF/PET Haemophobic/Hydrophobic Membrane	<input checked="" type="checkbox"/> RELEASED	

Bacterial Air Vent



PRODUCT DESCRIPTION	*Bacterial Air Vent made whit 1.2µm PVDF/PET Haemophobic/Hydrophobic Membrane			
INTENDED USE / APPLICATION	Describe application Air Vent for infusion set			
MATERIALS	P/N	Housing material	Filter media	COLOR
	TA156AFLEG012B00	Polyethylene	1.2 µm pore size PVDF/PET Haemofobic/hydrophobic membrane	White
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	<p>For raw materials used to produce components, Regulatory Documentation Required:</p> <p><u>raw material membrane:</u> Test performed in compliance with USP class VI and/or ISO 10993-1.</p> <p><u>raw material granule:</u> <u>Food contact</u> European Pharmacopoeia 1.3. "Polyolefines" (5th edition - 2005) USA USP 28 "POLYETHYLENE CONTAINERS"</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	11,60 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:</p> <ul style="list-style-type: none"> - Quantity - Product description - Product date - Lot number (OL and batch number to trace back to raw materials used) - Operator code <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 9001:2015, 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	
ACCEPTABLE QUALITY LEVEL	AQL with sampling Plan: ISO 2859 part.1	

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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	Sampling plan according to ISO 2859 part. 1 – 1 st Level inspection, single sampling plan, normal inspection.
	2 Deformations/squeezed parts	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 Plastic infiltration > 0,2 mm of 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 Serious mould, rust dirty	0,1	
	11 Flashes > 0,4 mm	1	
	12 Plastic infiltration < 0,2 mm of membrane surface	1	
	13 Jutting membrane threads	1	
	14 *Embedded particulate matter > 0,1 mm ²	1,5	
	15 Incompleteness's not compromising the functionality of the part	1,5	
	16 Not uniform coloring/streaks	1,5	
	17 Marks or Scrapes	1,5	
	18 Dirty, grease or rust on the part	1,5	
	19 *Loose contamination > 0,1 mm ²	1,5	

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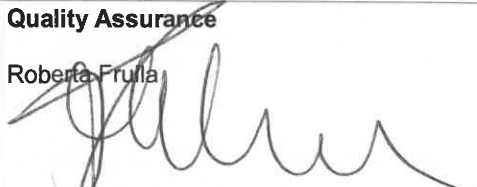
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DIMENSIONAL REQUIREMENTS															
	<table><tr><th colspan="2">Acceptance Requirement</th><th>Value of reference</th><th>AQL</th><th>Sampling Plan</th></tr><tr><td>1</td><td>Internal diameter</td><td>6,27±0.05mm gauge go/no go</td><td>0.1</td><td>Sampling plan according to ISO 2859 part. 1 – S3 Special inspection level, single sampling plan, normal inspection.</td></tr></table>				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.	
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PERFORMANCE REQUIREMENTS															
	<table><tr><th colspan="2">Functional Testing</th><th>AQL</th><th>Sampling Plan</th></tr><tr><td>Air flow</td><td>≥60 cc/min @ 50mbar</td><td>0,1</td><td rowspan="2">Sampling plan according to ISO 2859 part. 1 – S3 Special inspection level, single sampling plan, normal inspection.</td></tr><tr><td>Water Break Through</td><td>≥ 0,15 bar for 2 min</td><td>1</td></tr></table>				Functional Testing		AQL	Sampling Plan	Air flow	≥60 cc/min @ 50mbar	0,1	Sampling plan according to ISO 2859 part. 1 – S3 Special inspection level, single sampling plan, normal inspection.	Water Break Through	≥ 0,15 bar for 2 min	1
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Water Break Through	≥ 0,15 bar for 2 min	1													

***Note:** WBT test method, ramped pressure from 0 to 0,15bar 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)
09/06/2021	00	First issue	Project Manager Fausto Lentini	Director Quality Assurance Tiziana Landi
05/10/2021	01	Add new code	Project Manager Marco Piazzì 	Quality Assurance Roberta Frulla 



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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.