

PRODUCT SPECIFICATION

Product PN	TA140AFLEG030B00 TA140AFLEG030D00	<input type="checkbox"/> PRELIMINARY	Mod. 984c Rev. 05
		<input type="checkbox"/> R&D RELEASED	
Description	Air Vent with cap and hydrophobic membrane	<input checked="" type="checkbox"/> RELEASED	

Air vent with cap hydrophobic membrane



PRODUCT DESCRIPTION	Bacterial air vent with hydrophobic membrane as filter material, 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 contamination during usage.														
MATERIALS	<table><tr><th>P/N</th><th>Housing material</th><th>Filter media</th><th>COLOR</th></tr><tr><td>TA140AFLEG030B00</td><td>Polyethylene (PE)+ masterbatch</td><td rowspan="2">3,0 µm pore size membrane hydrophobic PVDF/PET</td><td>White</td></tr><tr><td>TA140AFLEG030D00</td><td>Polyethylene (PE)+ masterbatch</td><td>Blue</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 granule:</u> Food contact European Pharmacopoeia 1.3. "Polyolefines"(5th edition - 2005) USA USP 28 "POLYETHYLENE CONTAINERS"</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				P/N	Housing material	Filter media	COLOR	TA140AFLEG030B00	Polyethylene (PE)+ masterbatch	3,0 µm pore size membrane hydrophobic PVDF/PET	White	TA140AFLEG030D00	Polyethylene (PE)+ masterbatch	Blue
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PRODUCT CHARACTERISTICS	<table border="1"> <thead> <tr> <th colspan="2">Dimensions:</th></tr> </thead> <tbody> <tr> <td>Total height open without cap</td><td>14,10 mm</td></tr> <tr> <td>Total height with cap closed</td><td>15,10 mm</td></tr> <tr> <td>Total width</td><td>27,6 mm</td></tr> <tr> <td>Outside diameter (assembling side)</td><td>8,8 mm</td></tr> <tr> <td>Internal diameter (assembling side)</td><td>6,15 mm</td></tr> </tbody> </table>	Dimensions:		Total height open without cap	14,10 mm	Total height with cap closed	15,10 mm	Total width	27,6 mm	Outside diameter (assembling side)	8,8 mm	Internal diameter (assembling side)	6,15 mm
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STERILIZATION	<input checked="" type="checkbox"/> EtO; <input checked="" type="checkbox"/> Gamma (Max 25kGy);												
PRODUCT SHELF LIFE	5 years												
PACKAGING AND LABELLING	<p>20.000 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, ISO 13485.</p>												
DRAWING	<p>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</p>												

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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	Membrane double	0,1	
6	Membrane broken	0,1	
7	Membrane crushed	0,1	
8	Membrane residual on the part	0,1	
9	Bubbles	0,1	
10	Mixed components	0,1	
11	Grease / dirt within fluid path (assembling side)	0,1	
12	*Loose contamination > 0,1 mm ² within fluid path (assembling side)	0,1	
13	Flashes > 0,4 mm within fluid path (assembling side)	0,1	
14	Jutting injection gate > 0,2 mm	1	
15	Plastic infiltration 0,5 mm of the filter surface	1	
16	Threads	1	
17	*Embedded particulate matter > 0,1 mm ²	1,5	
18	Not uniform coloring/streaks	1,5	
19	Scrapes	1,5	
20	Dirty, grease or rust not within fluid path (side of the cap)	1,5	
21	*Loose contamination > 0,1 mm ² not within fluid path (side of the cap)	1,5	
22	Flashes > 0,4 mm not within fluid path (side of the cap)	1,5	

* Embedded Particulate Matter and Loose particulate matter: according to Dirt Estimation Chart

DIMENSIONAL REQUIREMENTS

Acptance Requirement			AQL	Sampling Plan
1	Internal diameter	6,15 ± 0.05 mm (Gauge go/no go)	0,1	ISO 2859 part. 1 S3 Special inspection level -



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PERFORMANCE REQUIREMENTS

Acceptance Requirement		Value of reference	AQL	Sampling Plan
1	Air Flow	≥ 75 scc/min @ 15 mbar	0,1	ISO 2859 part. 1 – S3 Special inspection level
2	*Water Break Through	0,08 bar for 5 minute.	0,1	
3	Air cap tightness	0,6 bar for 15 sec	0,1	

***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.