

PRODUCT SPECIFICATION

Product PN TA161BEPTG002B00 - TA161BEPTG012B00 - TA161BEPTG012C00 - TA161BEPTG030B00 - TA161BEPTG030C00 - TA161BEPTG030E00 - TA161BEPTG030U00	<input type="checkbox"/> PRELIMINARY <input type="checkbox"/> R&D RELEASED <input checked="" type="checkbox"/> RELEASED	Mod. 984c Rev. 05
Description Air vent with cap in PP with PVDF membrane / 0.2; 1.2 , 3.0 micron	<input checked="" type="checkbox"/> RELEASED	

Air vent with cap



PRODUCT DESCRIPTION	Air vent with cap in PP with PVDF membrane / 0.2 micron; 1.2 micron; 3.0 micron																													
INTENDED USE / APPLICATION	Is a non-sterile air vent with cap with membrane Hydrophobic The product is provided in bulk packs for further manufacturing																													
MATERIALS	<table><tr><th>P/N</th><th>Housing material</th><th>Filter media</th><th>COLOR</th></tr><tr><td>TA161BEPTG002B00</td><td rowspan="7">Polypropylene</td><td>0.2 µm pore size membrane hydrophobic PVDF/PET</td><td>White</td></tr><tr><td>TA161BEPTG012B00</td><td>1.2 µm pore size membrane hydrophobic PVDF/PET</td><td>White</td></tr><tr><td>TA161BEPTG012C00</td><td>1.2 µm pore size membrane hydrophobic PVDF/PET</td><td>Red</td></tr><tr><td>TA161BEPTG030B00</td><td>3 µm pore size membrane hydrophobic PVDF/PET</td><td>White</td></tr><tr><td>TA161BEPTG030C00</td><td>3 µm pore size membrane hydrophobic PVDF/PET</td><td>Red</td></tr><tr><td>TA161BEPTG030E00</td><td>3 µm pore size membrane hydrophobic PVDF/PET</td><td>Green</td></tr><tr><td>TA161BEPTG030U00</td><td>3 µm pore size membrane hydrophobic PVDF/PET</td><td>Blue</td></tr></table> <p>For raw materials used to produce components, Regulatory Documentation Required: <u>raw material:</u> membrane Test performed in compliance with USP class VI and/or ISO 10993-1.</p> <p><u>raw material granule:</u> Food contact European Pharmacopoeia1.3. "Polyolefines"(5th edition - 2005) USA USP 28 "POLYETHYLENE CONTAINERS"</p> <p>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>				P/N	Housing material	Filter media	COLOR	TA161BEPTG002B00	Polypropylene	0.2 µm pore size membrane hydrophobic PVDF/PET	White	TA161BEPTG012B00	1.2 µm pore size membrane hydrophobic PVDF/PET	White	TA161BEPTG012C00	1.2 µm pore size membrane hydrophobic PVDF/PET	Red	TA161BEPTG030B00	3 µm pore size membrane hydrophobic PVDF/PET	White	TA161BEPTG030C00	3 µm pore size membrane hydrophobic PVDF/PET	Red	TA161BEPTG030E00	3 µm pore size membrane hydrophobic PVDF/PET	Green	TA161BEPTG030U00	3 µm pore size membrane hydrophobic PVDF/PET	Blue
P/N	Housing material	Filter media	COLOR																											
TA161BEPTG002B00	Polypropylene	0.2 µm pore size membrane hydrophobic PVDF/PET	White																											
TA161BEPTG012B00		1.2 µm pore size membrane hydrophobic PVDF/PET	White																											
TA161BEPTG012C00		1.2 µm pore size membrane hydrophobic PVDF/PET	Red																											
TA161BEPTG030B00		3 µm pore size membrane hydrophobic PVDF/PET	White																											
TA161BEPTG030C00		3 µm pore size membrane hydrophobic PVDF/PET	Red																											
TA161BEPTG030E00		3 µm pore size membrane hydrophobic PVDF/PET	Green																											
TA161BEPTG030U00		3 µm pore size membrane hydrophobic PVDF/PET	Blue																											
PRODUCT CHARACTERISTICS	Dimensions: Outside diameter (assembling side) 8,43 mm Internal diameter (assembling side) 6,00 mm																													
PRODUCT SHELF LIFE	5 years																													
STERILIZATION	Eto																													

PRODUCT SPECIFICATION

Product PN		TA161BEPTG002B00 - TA161BEPTG012B00 - TA161BEPTG012C00 - TA161BEPTG030B00 - TA161BEPTG030C00 - TA161BEPTG030E00 - TA161BEPTG030U00		<input type="checkbox"/> PRELIMINARY <input type="checkbox"/> R&D RELEASED		Mod. 984c Rev. 05															
Description		Air vent with cap in PP with PVDF membrane / 0.2; 1.2 , 3.0 micron		<input checked="" type="checkbox"/> RELEASED																	
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: <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 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 9001:2015, 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.																			
ACCEPTABLE QUALITY LEVEL		AQL (see the below table)																			
VISUAL REQUIREMENTS		<p><i>Visual acceptance requirements apply when inspected under below conditions:</i></p> <p>Magnification: 3X Light type: light source Timings: 5 sec</p> <table><thead><tr><th colspan="2">Acceptance Requirement</th><th>AQL</th><th>Sampling Plan</th></tr></thead><tbody><tr><td>1</td><td>1. Incomplete plastic support 2. Deformation of plastic support, shrinkages of material 3. Incomplete, misplaced, missing membrane 4. Double or partially double membrane. 5. Membrane broken, pierced, crushed 6. Infiltration>0.2mm of material membrane surface 7. Part with broken or missing cap 8. Membrane incorporated residual 9. Internal cap deformation (bubble) 10. Serious mould, rust dirty</td><td>0,1</td><td rowspan="3">ISO 2859-1 (Table I) 1st general inspection level</td></tr><tr><td>2</td><td>11. Flashes > 0,4 mm 12. Infiltration ≤0.2mm of the membrane surface 13. Jutting membrane threads</td><td>1</td></tr><tr><td>3</td><td>14. *Embedded particulate matter > 0,1 mm² 15. Color not uniform 16. Marks or scratches 17. Incompleteness's not compromising the functionality of the part 18. Slight mould, rust dirty. 19. *Loose particulate matter > 0,1 mm²</td><td>1,5</td></tr></tbody></table> <p>*according to Dirt Estimation Chart (Tappi Standard). The characteristics above listed are statistically inspected during the manufacturing process.</p>						Acceptance Requirement		AQL	Sampling Plan	1	1. Incomplete plastic support 2. Deformation of plastic support, shrinkages of material 3. Incomplete, misplaced, missing membrane 4. Double or partially double membrane. 5. Membrane broken, pierced, crushed 6. Infiltration>0.2mm of material membrane surface 7. Part with broken or missing cap 8. Membrane incorporated residual 9. Internal cap deformation (bubble) 10. Serious mould, rust dirty	0,1	ISO 2859-1 (Table I) 1 st general inspection level	2	11. Flashes > 0,4 mm 12. Infiltration ≤0.2mm of the membrane surface 13. Jutting membrane threads	1	3	14. *Embedded particulate matter > 0,1 mm ² 15. Color not uniform 16. Marks or scratches 17. Incompleteness's not compromising the functionality of the part 18. Slight mould, rust dirty. 19. *Loose particulate matter > 0,1 mm ²	1,5
Acceptance Requirement		AQL	Sampling Plan																		
1	1. Incomplete plastic support 2. Deformation of plastic support, shrinkages of material 3. Incomplete, misplaced, missing membrane 4. Double or partially double membrane. 5. Membrane broken, pierced, crushed 6. Infiltration>0.2mm of material membrane surface 7. Part with broken or missing cap 8. Membrane incorporated residual 9. Internal cap deformation (bubble) 10. Serious mould, rust dirty	0,1	ISO 2859-1 (Table I) 1 st general inspection level																		
2	11. Flashes > 0,4 mm 12. Infiltration ≤0.2mm of the membrane surface 13. Jutting membrane threads	1																			
3	14. *Embedded particulate matter > 0,1 mm ² 15. Color not uniform 16. Marks or scratches 17. Incompleteness's not compromising the functionality of the part 18. Slight mould, rust dirty. 19. *Loose particulate matter > 0,1 mm ²	1,5																			

PRODUCT SPECIFICATION

Product PN	TA161BEPTG002B00 - TA161BEPTG012B00 - TA161BEPTG012C00 - TA161BEPTG030B00 - TA161BEPTG030C00 - TA161BEPTG030E00 - TA161BEPTG030U00	<input type="checkbox"/> PRELIMINARY <input type="checkbox"/> R&D RELEASED	Mod. 984c Rev. 05
Description	Air vent with cap in PP with PVDF membrane / 0.2; 1.2 , 3.0 micron	<input checked="" type="checkbox"/> RELEASED	

PERFORMANCE REQUIREMENTS

Filter PN	Air flow	WBT	Air CAP tightness	AQL
TA161BEPTG002B00	≥15 scc/min Pressure 10,2 cm/H2O	*Pressure 0,5 bar for 2 min	0,5 bar for 1 min	AQL 0,1 ISO 2859 part. 1 S3 Special inspection level -
TA161BEPTG012B00	≥65 scc/min Pressure 20 cm/H2O	*Pressure 0,15 bar for 2 min	0,5 bar for 1 min	
TA161BEPTG012C00				
TA161BEPTG030B00	≥40 scc/min Pressure 10 cm/H2O	*Pressure 0.08bar for 5 min	0,5 bar for 15 sec	
TA161BEPTG030E00			0,9 bar for 15 sec	
TA161BEPTG030U00				
TA161BEPTG030C00				


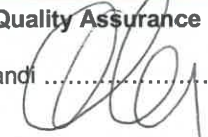
*Note: WBT test method, ramped pressure from 0 to specific final pressure (see WBT for each code) in 10 seconds

Acceptance Requirement			AQL	Sampling Plan
1	Dimendional assembling diameter	internal diameter 6 +/- 0,05 mm	0,1	ISO 2859 part. 1 S3 Special inspection level -
2	Dimendional assembling diameter	internal diameter 8,43 +/- 0,03 mm	0,1	

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)
04/06/2021	01	This version replaced the previous rev. 00. In Rev.01 has been change : 1) WBT performance for the part numbers: TA161BEPTG012... ; TA161BEPTG002... 2) Correct the tolerance dimension for internal and external diameter .	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.