

PRODUCT SPECIFICATION

Product PN	TA225BV29W010D01 - TA225CV29W010D01 TA225BV29W001D01 - TA225CV29W001D01 TA225BV29W001E01 - TA225CV29W001E01	☐ PRELIMINARY ☐ R&D RELEASED	Mod. 984c Rev. 05
Description	Bacterial Air Vent with female luer lock made whit 1,0 and 0,1µm PTFE/PP Hydrophobic Membrane	☒ RELEASED	

Bacterial Air Vent



PRODUCT DESCRIPTION	Bacterial air vent suitable for any type of Male Luer Slip, Male Luer Lock or Rotating Male Luer Lock with. Made whit1,0 µm and 0,1µm PTFE/PP Hydrophobic Membrane Non-sterile vent. The product is provided in bulk packs for further manufacturing.																				
INTENDED USE / APPLICATION	Air Vent with Female for infusion set																				
MATERIALS	<table><tr><th>Part number</th><th>Membrane</th><th>Frame/Housing</th><th>Color</th></tr><tr><td>TA225BV29W010D01</td><td rowspan="2">Hydrophobic membrane 1,0 µm PTFE</td><td rowspan="4">Polypropylene (PP) + Masterbatch</td><td rowspan="4">Blue</td></tr><tr><td>TA225CV29W010D01</td></tr><tr><td>TA225BV29W001D01</td><td rowspan="2">Hydrophobic membrane 0,1 µm PTFE</td></tr><tr><td>TA225CV29W001D01</td></tr><tr><td>TA225BV29W001E01</td><td rowspan="2">Hydrophobic membrane 0,1 µm PTFE</td><td rowspan="2">Polypropylene (PP) + Masterbatch</td><td rowspan="2">Green</td></tr><tr><td>TA225CV29W001E01</td></tr></table>				Part number	Membrane	Frame/Housing	Color	TA225BV29W010D01	Hydrophobic membrane 1,0 µm PTFE	Polypropylene (PP) + Masterbatch	Blue	TA225CV29W010D01	TA225BV29W001D01	Hydrophobic membrane 0,1 µm PTFE	TA225CV29W001D01	TA225BV29W001E01	Hydrophobic membrane 0,1 µm PTFE	Polypropylene (PP) + Masterbatch	Green	TA225CV29W001E01
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	For raw materials used to produce components: - Membrane: USP plastic Class VI – USP 88 - Granule: USP 661																				
	Regulatory Documentation: ☑ Rohs, directive 2002/95/CE ☑ BSE/TSE, directive 2003/32/CE ☑ DEHP plasticizer Free and latex free ☑ Reach 1907/2006/CE (hazardous substances regulation) ☑ Conflict minerals																				

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PRODUCT CHARACTERISTICS	Dimensions:	
	Total height	18,60 mm
	External diameter	7,83 mm
PRODUCT CHARACTERISTIC	Female connector in compliance with ISO 80369-7	
STERILIZATION	☒ EtO; ☒ Gamma 25kGy;	
PACKAGING AND LABELLING	TA225BV29W010D01/ TA225CV29W010D01 (Blue) 25.000 pcs. TA225BV29W001D01/ TA225CV29W001D01 (Blue) 25.000 pcs. TA225BV29W001E01/ TA225CV29W001E01 (Green) 25.000 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.	
DRAWING	The 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 below table	

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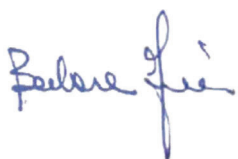
VISUAL REQUIREMENTS	Visual acceptance requirements apply when inspected under below conditions: Magnification: None Light type: naked eye + lamp + lens with 3x magnifier Timing: 5 sec per unit Distance: 30-45 cm				
	Acceptance Requirement			AQL	Sampling Plan
	1	Plastic support incomplete		0,1	ISO 2859 part. 1 1 st Level 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 squeezed		0,1	
	8	Plastic infiltration > 0,2 mm of the filter surface		0,1	
	9	Burns		0,1	
	10	Shrinkage on injection site		0,1	
	11	Membrane residual on the part		0,1	
	12	Bubbles		0,1	
	13	Dirty, grease on the part		0,1	
	14	Rust on the part		0,1	
	15	Flashes > 0,2 mm		1	
	16	Plastic infiltration < 0,2 mm of the filter surface		1	
	17	Threads		1	
	18	Jutting injection gate > 0,2 mm		1	
	19	*Embedded particulate matter > 0,3 mm ²		1,5	
	20	Not uniform coloring/streaks		1,5	
	21	Scrapes		1,5	
	22	Embedded or loosing dirt not compromising the functionality of the part		1,5	
	23	*Loose contamination >0,1mm ²		1,5	
	* Embedded Particulate Matter and Loose particulate matter: according to Dirt Estimation Chart				
PERFORMANCE REQUIREMENTS		Acceptance Requirement	Value of reference	AQL	Sampling Plan
	1	Internal diameter of female luer lock	4.248 +/- 0.05 mm 3.843 +/- 0.05 mm ISO 80369-7	0,1	ISO 2859 part. 1 – S3 Special inspection level

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FUNCTIONAL REQUIREMENTS	Item code		Acceptance Requirement	Reference Value	AQL	Sampling Plan
	TA225BV29W001D01	Air Flow	≥ 10 cc/min at 150 mbar	0,1	ISO 2859 part. 1 – S3 Special inspection level	
	TA225CV29W001D01	**Leakage test	1 bar for 5 min	0,1		
	TA225BV29W010D01	Air Flow	≥ 10 cc/min at 30 mbar	0,1		
	TA225CV29W010D01	**Leakage test	0.20 bar for 15 min	0,1		
	TA225BV29W001E01	Air Flow	≥ 10 cc/min at 150 mbar	0,1		
	TA225CV29W001E01	**Leakage test	1 bar for 5 min	0,1		
	NOTE _Test Condition: **Leakage test Method: ramped pressure from 0 to 0.20bar or 0 to 1.0bar 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)
01/08/2023	00	First issue	Silvio Tosi (AQP) Fausto Lentini (PM) Enrico Salvarani (RPROG) Luca Zanini (VP)	Barbara Finessi (QM)
11/12/2024	01	This revision replaces the previous rev.00. In the rev.01 it was added the part number. • TA225BV29W010D01 • TA225CV29W010D01	Silvio Tosi (AQP) Fausto Lentini (PM) Enrico Salvarani (RPROG) Luca Zanini (VP)	Barbara Finessi (QM)
01/07/2026	02	This revision replaces the previous rev.01. in the rev 02 the functional requirements were corrected and the part number was added: • TA225BV29W001E01 • TA225CV29W001E01	Sara Greco (AQP)  Antonio Berti (PM)  Enrico Salvarani (RPROG)  Luca Zanini (VP) 	Barbara Finessi (QM) 

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Customer Approval:

We accept this material specification as a part of the agreed terms of delivery

Company name _____

Approved by: _____

(Signature) _____ (Name, Function)

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.