

Product PN	TA225BV29G012D01-TA225BV29G012E01-TA225BV29G012I01- TA225CV29G012D01-TA225CV29G012E01-TA225CV29G012I01	<input type="checkbox"/> PRELIMINARY <input type="checkbox"/> R&D RELEASED <input checked="" type="checkbox"/> RELEASED	Mod. 984c Rev. 05
Description	Bacterial Air Vent with female luer lock made whit 1.2µm PVDF/PET Haemophobic / Hydrophobic Membrane		

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 whit 1.2µm PVDF/PET Haemophobic / 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	Part number	Membrane	Frame/Housing	Color
	TA225BV29G012D01	Haemophobic/hydrophobic membrane 1,2 µm PVDF	Polypropylene (PP) + Masterbatch	Blue
	TA225CV29G012D01			Blue
	TA225BV29G012E01			Green
	TA225CV29G012E01			Green
	TA225BV29G012I01			Orange
	TA225CV29G012I01			Orange
<p>For raw materials used to produce components, Regulatory Documentation Required: raw material membrane: Test performed in compliance with USP class VI and/or ISO 10993-1. raw material granule: Food contact European Pharmacopoeia 1.3. "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>				



PRODUCT SPECIFICATION

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PRODUCT CHARACTERISTICS	<table border="1" style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th colspan="2">Dimensions:</th> </tr> </thead> <tbody> <tr> <td>Total height</td> <td>18,60 mm</td> </tr> <tr> <td>External diameter</td> <td>7,83 mm</td> </tr> </tbody> </table>	Dimensions:		Total height	18,60 mm	External diameter	7,83 mm
Dimensions:							
Total height	18,60 mm						
External diameter	7,83 mm						
PRODUCT CHARACTERISTIC	Female connector in compliance with ISO 80369-7						
PRODUCT SHELF LIFE	5 years						
STERILIZATION	<input checked="" type="checkbox"/> EtO; <input checked="" type="checkbox"/> Gamma;						
PACKAGING AND LABELLING	<p>TA225BV29G012D01-TA225CV29G012D01 (Blue) 50.000 pcs. TA225BV29G012E01-TA225CV29G012E01 (Green) 50.000 pcs TA225BV29G012I01-TA225CV29G012I01 (Orange) 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:</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>With each shipment, GVS SpA Customer Service will send the CoC to the Customer, based on the lot numbers and date of manufacture. 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						
ACCEPTABLE QUALITY LEVEL	<input checked="" type="checkbox"/> AQL see below table						



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VISUAL REQUIREMENTS	<p>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</p>			
	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		
<p>* Embedded Particulate Matter and Loose particulate matter: according to Dirt Estimation Chart</p>				



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	Acceptance Requirement	Value of reference	AQL	Sampling Plan
PERFORMANCE REQUIREMENTS	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

	Acceptance Requirement	Value of reference	AQL	Sampling Plan
FUNCTIONAL REQUIREMENTS	1 * Air Flow	AF ≥ 20 scc/min at 20 mBar (20 cm H ₂ O)	0,1	ISO 2859 part. 1 – S3 Special inspection level
	2 Water Break Through	WBT ≥ 1800 mmH ₂ O for 15 min	0,1	

* **NOTE: Test Condition:** Priming time: 16" max - with 3.0x4.1x2000 mm (14.13 cm³) tube 1000 mm Water Head Pressure

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)
19/01/2021	00	First issue	Project Manager Fausto Lentini <i>Fausto Lentini</i>	Director Quality Assurance Tiziana Landi <i>Tiziana Landi</i>

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.