

PRODUCT SPECIFICATION

Product PN	TA222AV29G012A00	<input type="checkbox"/> PRELIMINARY	Mod. 984c Rev. 05
Description	Plug insert for catheter in PP with Hydrophobic membrane 1,2µm – Natural	<input checked="" type="checkbox"/> RELEASED	

Bacterial Air vent IV for Catheter



PRODUCT DESCRIPTION	Plug insert for catheter with PP frame Is a non-sterile filter with membrane 1,2 µm The product is provided in bulk packs for further manufacturing.											
INTENDED USE / APPLICATION	Bacterial Air vent IV for Catheter											
MATERIALS	<table border="1"> <thead> <tr> <th>P/N</th> <th>Housing material</th> <th>Filter media</th> <th>COLOR</th> </tr> </thead> <tbody> <tr> <td>TA222AV29G012A00</td> <td>PP</td> <td>1,2 µm pore size membrane hydrophobic PVDF/PET</td> <td>Natural</td> </tr> </tbody> </table>				P/N	Housing material	Filter media	COLOR	TA222AV29G012A00	PP	1,2 µm pore size membrane hydrophobic PVDF/PET	Natural
	P/N	Housing material	Filter media	COLOR								
TA222AV29G012A00	PP	1,2 µm pore size membrane hydrophobic PVDF/PET	Natural									
<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>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"/> Conflict minerals <input checked="" type="checkbox"/> Latex free <input checked="" type="checkbox"/> BPA and phthalates Free 												

PRODUCT SPECIFICATION

Product PN	TA222AV29G012A00	<input type="checkbox"/> PRELIMINARY	Mod. 984c Rev. 05
Description	Plug insert for catheter in PP with Hydrophobic membrane 1,2µm – Natural	<input checked="" type="checkbox"/> RELEASED	

PRODUCT CHARACTERISTICS	Dimensions:	
	Weight	0.35 g
	Total height	20 ± 0.1mm
STERILIZATION	<input checked="" type="checkbox"/> EtO; <input checked="" type="checkbox"/> Gamma (Max 25kGy);	
PACKAGING AND LABELLING	<p>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.</p> <p>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</p> <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 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>	

PRODUCT SPECIFICATION

Product PN	TA222AV29G012A00	<input type="checkbox"/> PRELIMINARY	Mod. 984c Rev. 05
Description	Plug insert for catheter in PP with Hydrophobic membrane 1,2µm – Natural	<input checked="" type="checkbox"/> RELEASED	

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, single sampling plan, normal inspection.
	2	Deformation of plastics support, shrinkages of material	0,1	
	3	Membrane broken	0,1	
	4	Incomplete, missing membrane	0,1	
	5	Double or partially membrane	0,1	
	6	Plastic Infiltration >0.2mm around molding board	0,1	
	7	Flashes at top of the luer cone > 0.2 mm	0,1	
	8	Jutting injection gate >0.5 mm	1.5	
	9	External flashes >0.5 mm	1.5	
	10	Plastic or membrane threads	1.5	
	11	Plastic Infiltration ≤0.2mm around molding board	1.5	
	11	*Embedded particulate matter > 0,3 mm ²	1.5	
	12	Color not uniform	1,5	
	13	Marks or Scratches	1,5	
	14	Incompleteness not compromising the functionality of the part	1,5	
15	Mold rust dirty	1,5		
16	Loose particulate matter > 0,1 mm ²	1.5		
<p>The characteristics above listed are statistically inspected during the manufacturing process. * Embedded Particulate Matter: according to Dirt Estimation Chart (Tappi Standard).</p>				

PRODUCT SPECIFICATION

Product PN	TA222AV29G012A00	<input type="checkbox"/> PRELIMINARY <input type="checkbox"/> R&D RELEASED <input checked="" type="checkbox"/> RELEASED	Mod. 984c Rev. 05
Description	Plug insert for catheter in PP with Hydrophobic membrane 1,2µm – Natural		

DIMENSIONAL REQUIREMENTS	Acceptance Requirement		Value of reference	AQL	Sampling Plan
	1	External cone diameter	Gauge go/ not go	0,1	ISO 2859 part. 1 – S3 Special inspection level

PERFORMANCE REQUIREMENTS	Acceptance Requirement		Value of reference	AQL	Sampling Plan
	1	Air Flow	≥ 10 cc/min (Pressure 30 mBar)	0,1	ISO 2859 part. 1 – S3 Special inspection level
2	*Water Break Through	0,1 bar for 5 minute.	0,1		

***Note:** WBT test method, ramped pressure from 0 to 0,1 bar 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)
22/03/2022	00	First issue	Project Manager Fausto Lentini 	Director Quality Assurance GVS Sud Roberta Frulla 

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.