

Product PN	TP027ANAL002AV01	□ PRELIMINARY	
	TP027ANAV002AV01 TP027ANAV010AV01	□R&D RELEASED	Mod. 984c
Description	Transducer Protector – PVC- membrane - clear/blue	RELEASED	1104. 00

Transducer protector rigid PVC clear/blue with membrane



PRODUCT DESCRIPTION	Transducer protector Is a non-sterile transducer protector with membrane The product is provided in bulk packs for further manufacturing
INTENDED USE / APPLICATION	Vent device
MATERIALS	TPO27ANAL002AV01 Membrane: hydrophilic Membrane AC 0,2 μm on a non-woven Nylon Support Housing: males cone rigid PVC Phthalate free (one side clear / other side blue) TPO27ANAV010AV01 Membrane: hydrophobic Membrane PTFE 1 μm on a non-woven Polyester Support Housing: males cone rigid PVC Phthalate free (one side clear / other side blue) TPO27ANAV002AV01 Membrane: hydrophobic Membrane PTFE 0.2 μm on a non-woven Polyester Support Housing: males cone rigid PVC Phthalate free (one side clear / other side blue) For raw materials used to produce components, Regulatory Documentation Required: ☑ Test performed in compliance with USP class VI and/or ISO 10993-1. ☑ Reach 1907/2006/CE (hazardous substances regulation) in compliance ☑ BSE/TSE, Free ☑ DEHP plasticizer Free ☑ Latex free ☑ Conflict minerals



TP TP Description Tra	027ANAL002AV01 027ANAV002AV01 027ANAV010AV01 nsducer Protector – PVC- membrane -	□ PRELIMINARY □ R&D RELEASED □ RELEASED	Mod. 984c Rev. 05			
PRODUCT CHARACTERISTICS	Dimensions: External diameter 27,5 mm Filter height 46,7 mm Total weight 4,0 gr					
STERILIZATION	STERILE:					
APPLICABLE STANDARDS AND REGULATIONS	In compliance with ISO 80369-7:2016 Connectors with 6% (Luer) taper for intravascular or hypodermic applications					
PACKAGING AND LABELLING	5.000 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 complies with ISO 9001, 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: with sampling Plan: ISO 2859 part. 1					



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VISUAL REQUIREMENTS

Visual acceptance requirements apply when inspected under below conditions:

Instrument inspection with naked eye and light source **Distance** of 300-450 mm.

Timings: 5 sec per unit

	Acceptance Requirement	AQL	Sampling Plan
1	 Incomplete plastic support. Damaged, deformed, cracked parts. Burrs > 0,2 mm. Jutting injection gate > 0,2 mm. Broken or dented connectors. Holes on membrane / mesh surface. Membrane / mesh jutting outside the housings. Parts with not complete or misplaced membrane / mesh. Parts with double membrane Folds on the membrane diameter with presence of leakage Detachable threads and loose PM. 	0,4	ISO 2859 part. 1 1 st Level normal
2	 12. *Embedded black spots > 0,2 mm² (max 3 per viewing area). 13. *Burnings on the welding area > 0,2 mm² 14. Coloring not uniform. 15. *Bubbles in plastic support > 0,4 mm² (max 3 per viewing area). 16. Scratches with no plastic residuals 	1,5	inspection

^{*}Embedded Particulate Matter, burnings and air bubbles: according to Dirt Estimation Chart (Tappi Standard).

PERFORMANCE REQUIREMENTS

Filter PN	Membrane	WFR	WBP	Burst test	AQL	Sampling Plan
TP027ANAL002AV01	Hydrophilic AC-NY 0,2 μm	Pressure 800 mmH ₂ O > 30 ml 5 min	Pressure 1 bar Time test 1 minute	3 bar 15 sec	0,1	ISO 2859 part. 1 S3 Special inspection level



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PERFORMANCE REQUIREMENTS

Filter PN	Membrane	Air Flow	WBT	Burst test	AQL	Sampling Plan
TP027ANAV010AV01	Hydrophobic PTFE 1,0 µm	Pressure 5 mbar ≥ 120 scc/min	Pressure 0,1 bar Time test 1 minute	3 bar 15 sec	0,1	ISO 2859 part. 1
TP027ANAV002AV01	Hydrophobic PTFE 0,2 µm	Pressure 5 mbar ≥ 55 scc/min	Pressure 1 bar Time test 1 minute	3 bar 15 sec	0,1	S3 Special inspection level

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)
23/06/2020	03	This revision replaces the previous. In this Rev. it was added the compliance with ISO 80369-7:2016	Isabella Frignani Process Quality Assurance	Tiziana Landi Director Quality Assurance

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.