

# PRODUCT SPECIFICATION

Product PN	TP027ANAL002AV01 TP027ANAV002AV01 TP027ANAV010AV01	<input type="checkbox"/> PRELIMINARY <input type="checkbox"/> R&D RELEASED	Mod. 984c Rev. 05
Description	Transducer Protector – PVC- membrane - clear/blue	<input checked="" type="checkbox"/> RELEASED	

**Transducer protector rigid PVC clear/blue with membrane**



<b>PRODUCT DESCRIPTION</b>	<p>Transducer protector Is a non-sterile transducer protector with membrane The product is provided in bulk packs for further manufacturing</p>
<b>INTENDED USE / APPLICATION</b>	Vent device
<b>MATERIALS</b>	<p><b>TP027ANAL002AV01</b> 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 )</p> <p><b>TP027ANAV010AV01</b> 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 )</p> <p><b>TP027ANAV002AV01</b> 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 )</p> <p><b>For raw materials used to produce components, Regulatory Documentation Required:</b></p> <ul style="list-style-type: none"> <li><input checked="" type="checkbox"/> Test performed in compliance with USP class VI and/or ISO 10993-1.</li> <li><input checked="" type="checkbox"/> Reach 1907/2006/CE (hazardous substances regulation) in compliance</li> <li><input checked="" type="checkbox"/> Rohs in compliance</li> <li><input checked="" type="checkbox"/> BSE/TSE, Free</li> <li><input checked="" type="checkbox"/> DEHP plasticizer Free</li> <li><input checked="" type="checkbox"/> Latex free</li> <li><input checked="" type="checkbox"/> Conflict minerals</li> </ul>



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<b>VISUAL REQUIREMENTS</b>	<p><i>Visual acceptance requirements apply when inspected under below conditions:</i></p> <p><b>Instrument inspection</b> with naked eye and light source  <b>Distance</b> of 300-450 mm.  <b>Timings:</b> 5 sec per unit</p>																			
	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr style="background-color: #cccccc;"> <th style="width: 5%;"></th> <th style="width: 75%;">Acceptance Requirement</th> <th style="width: 10%;">AQL</th> <th style="width: 10%;">Sampling Plan</th> </tr> </thead> <tbody> <tr> <td style="text-align: center; vertical-align: top;">1</td> <td>           1. Incomplete plastic support.            2. Damaged, deformed, cracked parts.            3. Burrs &gt; 0,2 mm.            4. Jutting injection gate &gt; 0,2 mm.            5. Broken or dented connectors.            6. Holes on membrane / mesh surface.            7. Membrane / mesh jutting outside the housings.            8. Parts with not complete or misplaced membrane / mesh.            9. Parts with double membrane            10. Folds on the membrane diameter with presence of leakage            11. Detachable threads and loose PM.         </td> <td style="text-align: center; vertical-align: middle;">0,4</td> <td rowspan="2" style="text-align: center; vertical-align: middle;">ISO 2859 part. 1 1<sup>st</sup> Level normal inspection</td> </tr> <tr> <td style="text-align: center; vertical-align: top;">2</td> <td>           12. *Embedded black spots &gt; 0,2 mm<sup>2</sup> (max 3 per viewing area).            13. *Burnings on the welding area &gt; 0,2 mm<sup>2</sup>            14. Coloring not uniform.            15. *Bubbles in plastic support &gt; 0,4 mm<sup>2</sup> (max 3 per viewing area).            16. Scratches with no plastic residuals         </td> <td style="text-align: center; vertical-align: middle;">1,5</td> </tr> </tbody> </table> <p>*Embedded Particulate Matter, burnings and air bubbles: according to Dirt Estimation Chart (Tappi Standard).</p>							Acceptance Requirement	AQL	Sampling Plan	1	1. Incomplete plastic support. 2. Damaged, deformed, cracked parts. 3. Burrs > 0,2 mm. 4. Jutting injection gate > 0,2 mm. 5. Broken or dented connectors. 6. Holes on membrane / mesh surface. 7. Membrane / mesh jutting outside the housings. 8. Parts with not complete or misplaced membrane / mesh. 9. Parts with double membrane 10. Folds on the membrane diameter with presence of leakage 11. Detachable threads and loose PM.	0,4	ISO 2859 part. 1 1 <sup>st</sup> Level normal inspection	2	12. *Embedded black spots > 0,2 mm <sup>2</sup> (max 3 per viewing area). 13. *Burnings on the welding area > 0,2 mm <sup>2</sup> 14. Coloring not uniform. 15. *Bubbles in plastic support > 0,4 mm <sup>2</sup> (max 3 per viewing area). 16. Scratches with no plastic residuals	1,5			
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FILTER TECHNOLOGY

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Description	Transducer Protector – PVC- membrane - clear/blue		

<b>PERFORMANCE REQUIREMENTS</b>	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 S3 Special inspection level
	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	

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.