

PRODUCT SPECIFICATION

Product PN **TP030ANAV002AA02**
TP030ANAV010AA02
TP030BNAR002AA02

Mod. 984

Rev. 02

Description Transducer protector - clear/clear – PVC - membrane

Transducer Protector - PVC - membrane



PRODUCT DESCRIPTION	<p>Transducer protector Is a non-sterile transducer protector with membrane (Hydrophobic PTFE 0,2 µm / Hydrophobic PTFE 1,0 µm / Hydrophobic AC 0,2 µm) The product is provided in bulk packs for further manufacturing</p>
INTENDED USE / APPLICATION	Air vent
MATERIALS	<p>TP030ANAV002AA02 Membrane: Hydrophobic PTFE Membrane 0,2 µm on Polyester non-woven support Housing: clear rigid PVC – one side with male cone luer the other side is plate</p> <p>TP030ANAV010AA02 Membrane: Hydrophobic PTFE Membrane 1,0 µm on Polyester non-woven support Housing: clear rigid PVC - one side with male cone luer the other side is plate</p> <p>TP030BNAR002AA02 Membrane: Hydrophobic AC-NY 0,2 µm on a non-woven Nylon Support Housing: clear rigid PVC - one side with male cone luer the other side is plate</p> <p>For raw materials used to produce components, Regulatory Documentation Required:</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Test performed in compliance with USP class VI and/or ISO 10993-1. <input checked="" type="checkbox"/> Reach 1907/2006/CE (hazardous substances regulation) <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 <input checked="" type="checkbox"/> Latex free <input checked="" type="checkbox"/> Conflict minerals <input checked="" type="checkbox"/> DOTE free (CAS 15571-58-1)
PRODUCT CHARACTERISTIC	<p>External diameter 27,35 mm Filter height 13,75 mm Total weight 2,2 gr</p>
STERILIZATION	Ethylene oxide
PACKAGING AND LABELLING	<p>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.</p> <p>Each bag is labeled with the following traceability information:</p>

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<p>PACKAGING AND LABELLING</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>											
<p>CERTIFICATE OF COMPLIANCE</p>	<p>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, ISO 13485.</p>											
<p>DRAWING</p>	<p>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.</p>											
<p>VISUAL REQUIREMENTS</p>	<p><i>Visual acceptance requirements apply when inspected under below conditions:</i> Instrument inspection with naked eye and light source Distance of 300-450 mm. Timings: 5 sec per unit</p> <table border="1" data-bbox="335 1164 1452 1870"> <thead> <tr> <th></th> <th>Acceptance Requirement</th> <th>AQL</th> <th>Sampling plan</th> </tr> </thead> <tbody> <tr> <td>1</td> <td> 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. </td> <td>0,4</td> <td rowspan="2">ISO 2859 part. 1 1st Level.</td> </tr> <tr> <td>2</td> <td> 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 </td> <td>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 st Level.	2	12. *Embedded black spots > 0,2 mm ² (max 3 per viewing area). 13. *Burnings on the welding area > 0,2 mm ² 14. Coloring not uniform. 15. *Bubbles in plastic support > 0,4 mm ² (max 3 per viewing area). 16. Scratches with no plastic residuals	1,5
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PERFORMANCE REQUIREMENTS	Filter PN	Membrane Hydrophobic	Air flow	WBT	Air leakage	Burst test	Dimensional	Sampling plan
	TP030ANAV002AA02	Hydrophobic PTFE 0,2 µm	Pressure 50 mmH ₂ O ≥ 55 scc/min	Pressure 1 bar Time test 1 minute	0,7 bar 15 sec	3 bar 15 sec	Luer cone ISO594 (gauge go /no go)	AQL 0,1 ISO 2859 part. 1 S3 Special inspection level
	TP030ANAV010AA02	Hydrophobic PTFE 1,0 µm	Pressure 50 mmH ₂ O ≥ 100 scc/min	Pressure 0,1 bar Time test 1 minute	0,7 bar 15 sec	3 bar 15 sec		
	TP030BNAR002AA02	Hydrophobic AC 0,2 µm	Pressure 50 mmH ₂ O ≥ 15 scc/min	Pressure 1 bar Time test 1 minute	0,7 bar 15 sec	3 bar 15 sec		

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)
07/12/2017	06	This revision replaces the previous rev. 05. In this rev. 06 it was added the codes TP030ANAV010AA02 TP030BNAR002AA02	Domenico Romondia Project Engineering 	Isabella Frignani Process 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.