

PRODUCT SPECIFICATION

Product PN TP026ANAR002AA01 – TP026ANAV002AC01
TP026ANAV002AV01 – TP026ANAV004AV01
TP026ANAV010AV01

Mod. 984 c

Rev. 04

Description Transducer protector – PVC – with Hydrophobic membrane

Transducer protector rigid PVC
clear/clear; clear/red or clear/blue
with membrane



PRODUCT DESCRIPTION	Transducer protector Is a non-sterile transducer protector with membrane Hydrophobic or Hydrophilic The product is provided in bulk packs for further manufacturing
INTENDED USE / APPLICATION	Venting device
PRODUCT CHARACTERISTIC	<p>TP026ANAR002AA01 Membrane: Hydrophobic Membrane Ac-Ny 0,2µm Acrylic co-polymer on a non-woven Nylon support. Housing: male cone PVC clear male cone PVC clear</p> <p>TP026ANAV002AC01 Membrane: Hydrophobic Membrane PTFE 0,2 µm Acrylic co-polymer on a non-woven Polyester support. Housing: male cone PVC red male cone PVC clear</p> <p>TP026ANAV002AV01 Membrane: Hydrophobic Membrane PTFE 0,2 µm Acrylic co-polymer on a non-woven Polyester support. Housing: male cone PVC blue male cone PVC clear</p> <p>TP026ANAV004AV01 Membrane: Hydrophobic Membrane PTFE 0,45 µm Acrylic co-polymer on a non-woven Polyester support. Housing: male cone PVC blue male cone PVC clear</p> <p>TP026ANAV010AV01 Membrane: Hydrophobic Membrane PTFE 1 µm Acrylic co-polymer on a non-woven Polyester support. Housing: male cone PVC blue male cone PVC clear</p> <p>For raw materials used to produce components, Regulatory Documentation Required: <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 </p>

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STERILIZATION	Ethylene oxide													
APPLICABLE STANDARDS AND REGULATIONS	Dimensions of luer cones comply with ISO 80369-7													
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> <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>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>													
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.													
VISUAL REQUIREMENTS	<p>Visual acceptance requirements apply when inspected under below conditions:</p> <p>Instrument inspection with naked eye and light source Distance of 300-450 mm. Timings: 5 sec per unit</p>													
VISUAL REQUIREMENTS	<table> <tr> <th colspan="2">Acceptance Requirement</th><th>AQL</th><th>Sampling Plan</th></tr> <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">Sampling plan according to ISO 2859 part. 1 – 1st Level inspection, single sampling plan, normal inspection.</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> </table>			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	Sampling plan according to ISO 2859 part. 1 – 1 st Level inspection, single sampling plan, normal inspection.	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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**Embedded Particulate Matter, burnings and air bubbles : according to Dirt Estimation Chart (Tappi Standard).

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PERFORMANCE REQUIREMENTS	Filter PN	Membrane Hydrophobic	Air flow	WBT	Burst test	AQL	Sampling Plan
	TP026ANAR002AA01	Hydrophobic AC-NY 0,2 µm	Pressure 50 mm/H ₂ O >=15 ml/min	Pressure 1 bar Time test 1 minute	3 bar 15sec	0,1	ISO 2859 part. 1 S3 Special inspection level
	TP026ANAV002AC01	Hydrophobic PTFE 0,2 µm	Pressure 50 mm/H ₂ O >=55 ml/min	Pressure 1 bar Time test 1 minute	3 bar 15sec		
	TP026ANAV002AV01	Hydrophobic PTFE 0,2 µm	Pressure 50 mm/H ₂ O >=55 ml/min	Pressure 1 bar Time test 1 minute	3 bar 15sec		
	TP026ANAV004AV01	Hydrophobic PTFE 0,45 µm	Pressure 50 mm/H ₂ O >=95 ml/min	Pressure 0,5 bar Time test 1 minute	3 bar 15sec		
	TP026ANAV010AV01	Hydrophobic PTFE 1,0 µm	Pressure 50 mm/H ₂ O >=100 ml/min	Pressure 0,1 bar Time test 1 minute	3 bar 15sec		
DIMENSIONAL REQUIREMENTS	Acceptance Requirement		Value of Reference		AQL	Sampling Plan	
	Internal diameter of Male luer lock (ISO 80369-7)		4,021 ± 0,051 mm 4,426 ± 0,050 mm		0,1	ISO 2859 part. 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)
04/09/2019	01	This revision replaces the previous. In this Rev. there is a changing of dimensional requirements for Luer Connectors	Martina Miele RP 	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.