

Product PN **TP038ANAV010AA02**

PRELIMINARY

Mod. 984c

R&D RELEASED

Rev. 05

Description Transducer protector-clear/clear-hydrophobic membrane 1 μ PTFE

RELEASED

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



PRODUCT DESCRIPTION	Transducer protector Is a non-sterile transducer protector with membrane Hydrophobic The product is provided in bulk packs for further manufacturing
INTENDED USE / APPLICATION	Air vent
MATERIALS	<p>Membrane: Hydrophobic Membrane PTFE 1,0 μm on Polyester non-woven support Housing: male cone PVC clear female cone PVC clear</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)
APPLICABLE STANDARDS AND REGULATIONS	Dimensions of luer cones in compliance with ISO 80369-7
PRODUCT CHARACTERISTIC	External diameter 27,4 mm Filter height 22,2 mm Total weight 2,4 gr
STERILIZATION	Ethylene oxide
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: <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
	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 is in compliance with ISO 9001, ISO 13485.



PRODUCT SPECIFICATION

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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

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	
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	

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

PERFORMANCE REQUIREMENTS

Air Flow	WBT	Air leakage	Burst test	Dimensional	AQL	Sampling Plan
Pressure 50 mm/H ₂ O > 100 scc/min	Pressure 0,1 bar Time test 1 minute	0,7 bar 15 sec	3 bar 15 sec	In compliance with ISO 80369-7 For Luer connectors	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.



PRODUCT SPECIFICATION

FILTER TECHNOLOGY

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REVISIONS AND APPROVALS:

DATE	REV.	REASON FOR CHANGE	ISSUED AND CONTROLLED BY: (name /function and signature)	APPROVED BY: (name /function and signature)
01/03/2022	01	Introduction of compliance with ISO80369-7 for Luer connectors.	Elsa Caruso Project Manager 	Roberta Frulla 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.