

PRODUCT SPECIFICATION

Product PN **TP010ARA0000AA00**

Mod. 984

Description **Pressure monitor isolator with flexible diaphragm**

Rev. 02

**Transducer isolator - Gamma resistance
PVC displacement membrane**



PRODUCT DESCRIPTION	Transducer protector Is a non-sterile transducer protector with PVC displacement membrane The product is provided in bulk packs for further manufacturing
MANUFACTURER NAME	GVS Sud S.r.l. Via Tavernole, 8 83030 Manocalzati (AV) – ITALY
INTENDED USE / APPLICATION	Cardiosurgery, Perfusion, Hemodialysis, Custom Kits.
MATERIALS	<p>Membrane: Soft No-DEHP PVC film Housing: male cone dome rigid gamma sterilizable rigid PVC clear 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
PRODUCT CHARACTERISTIC	<p>External diameter 38 mm Filter height 61 mm Total weight 5,8 gr</p>
STERILIZATION	Ethylene oxide, Gamma Ray (Max 25 KG)
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>

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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.

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. Burned pieces welding area.	0,4	Sampling plan according to ISO 2859 part. 1 – 1 st Level inspection, single sampling plan, normal inspection.
	2. Flashes > 0,2 mm.	0,4	
	3. Dents.	0,4	
	4. Dirty on membrane.	0,4	
	5. Hole on membrane.	0,4	
	6. Membrane height <7 mm.	0,4	
	7. Not much welding piece.	0,4	
	8. Internal loose plastic particles.	0,4	
	9. Metallic particles > 0,2 mm ² .	0,4	
	10. Critical deformations in the welding area.	0,4	
	11. Plastic components not aligned.	0,4	
	12. Black point on membrane > 0,2 mm ² .	0,4	
	13. Membrane not centered.	0,4	
	14. Fold on membrane.	0,4	
	15. Very evident sign on plastic components.	0,4	
2	1. *Black point on half case > 0,2 mm ² .	1,5	
	2. Scratches on plastic components.	1,5	

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

IFU

The transducer must be mounted with the bell facing the positive pressure.

In this way, the membrane returns towards the center and the transducer works in the field of deformation "of the form" and not in the elastic range.

If mounted on the contrary the pressure is the bell already completely swollen, and then the membrane is forced to work in the field "elastic"

So the pressure as well as winning the opposite pressure will win even the 'elasticity of the material giving a false reading.

The transducer being permeable but not of the type "displacement" must first be connected to the machine and then it must feed the circuit to be measured.

In extreme cases if you mount the workpiece to the membrane reverse can also clog the exit hole making ineffective the transducer.

In this case the diaphragm position must be re-established by inserting air with a syringe.

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PERFORMANCE REQUIREMENTS

Acceptance Requirement			AQL	Sampling Plan
1	Micro leaks test	130 mbar 5,5 sec 100% inspected	0,065	AQL 0,1 ISO 2859 part. 1 S3 Special inspection level
2	Burst test	6 bar 1 min	0,065	
3	Dimensional	Membrane shape height not conform < 7 mm	0,065	

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)
15/02/2017	00	First emission	Marco Piazzì – RP <i>Marco Piazzì</i> Isabella Frignani – AQP <i>Isabella Frignani</i>	Tiziana Landi – AQ <i>Tiziana Landi</i>

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.