

Product PN	TP010AAT0000AA00	<input type="checkbox"/> PRELIMINARY	Mod. 984c Rev. 05
Description	Pressure monitor isolator with flexible diaphragm	<input type="checkbox"/> R&D RELEASED <input checked="" type="checkbox"/> RELEASED	

Transducer protector



PRODUCT DESCRIPTION	<p>Transducer protector</p> <p>Is a non-sterile transducer protector with PVC displacement membrane</p> <p>The product is provided in bulk packs for further manufacturing</p>
MANUFACTURER NAME	<p>GVS Sud S.r.l.</p> <p>Via Tavernole, 8</p> <p>83030 Manocalzati (AV) – ITALY</p>
INTENDED USE / APPLICATION	<p>Cardiosurgery, Perfusion, Hemodialysis, Custom Kits.</p>
MATERIALS	<p>Membrane (Diaphragm) : Soft PVC film</p> <p>Housing: Male cone dome rigid PVC clear</p> <p>Color: Natural</p> <p>Regulatory Documentation Required:</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Biocompatibility according ISO 10993-1 <input type="checkbox"/> IMDS <input checked="" type="checkbox"/> Rohs, directive 2002/95/CE <input checked="" type="checkbox"/> BSE/TSE <input type="checkbox"/> DEHP plasticizer Free and latex free DEHP (CAS No 117-81-7) 0.72% <input type="checkbox"/> Aging <input type="checkbox"/> Reach 1907/2006/CE (hazardous substances regulation) DOTe (CAS No 15571-58-1) 0.93% DEHP (CAS No 117-81-7) 0.72% <input checked="" type="checkbox"/> Conflict minerals <p>Other <input checked="" type="checkbox"/> N/A <input type="checkbox"/> Specify:</p>

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PRODUCT CHARACTERISTIC	External diameter 38 mm Filter height 61 mm Total weight 5,8 gr Full-scale pressure 0.13bar Weld integrity 6 bar
INSTRUCTIONS WARNINGS	<p>IFU: The isolator must be mounted with the bell facing the positive pressure. In this way, the membrane returns towards the center and the isolator works in the field of deformation "of the form" and not in the elastic range.</p> <p>If mounted on the contrary the pressure is completely swelling the bell, and then the membrane is forced to work in the field "elastic"</p> <p>So the pressure as well as winning the opposite pressure will win even the 'elasticity of the material giving a false reading.</p> <p>The Isolator is a displacement type, not permeable must first be connected to the machine and then it must feed the circuit to be measured.</p> <p>In extreme cases if you mount the workpiece to the membrane reverse can also clog the exit hole making ineffective the transducer.</p> <p>In this case the diaphragm position must be re-established by inserting air with a syringe.</p>
STERILIZATION	<input type="checkbox"/> Not required; <input checked="" type="checkbox"/> EtO; <input type="checkbox"/> Gamma; <input type="checkbox"/> Beta; <input type="checkbox"/> Steam; <input type="checkbox"/> e-beam
PACKAGING AND LABELLING	<p>5.000 pcs packed in two PE bags. Bags are separately closed.</p> <p>The first bar-code label is between the 2 bags.</p> <p>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.</p> <p>Different lots in one box are separately closed and separately labeled to prevent mix-ups.</p> <p>Labelling: <input checked="" type="checkbox"/> Standard; <input type="checkbox"/> Customer specific:</p>
CERTIFICATE OF COMPLIANCE	<p>With each shipment, GVS SpA Customer Service will send the CoC to the Customer, based on the lot numbers and date of manufacture.</p> <p>Conformity declaration is printed on every invoice and Certificate is according to UNI EN 10204 type 2.1</p> <p>The Quality management system is in compliance with ISO 9001:2015, ISO 13485:2016, IATF 16949 2016</p>

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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.
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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	<div>1. Burned pieces welding area.</div> <div>2. Flashes > 0,2 mm.</div> <div>3. Dents.</div> <div>4. Dirty on membrane.</div> <div>5. Hole on membrane.</div> <div>6. Membrane height <7 mm.</div> <div>7. Not much welding piece.</div> <div>8. Internal loose plastic particles.</div> <div>9. Metallic particles > 0,2 mm².</div> <div>10. Critical deformations in the welding area.</div> <div>11. Plastic components not aligned.</div> <div>12. Black point on membrane > 0,2 mm².</div> <div>13. Membrane not centered.</div> <div>14. Fold on membrane.</div> <div>15. Very evident sign on plastic components.</div>	<div>0,4</div> <div>0,4</div> <div>0,4</div> <div>0,4</div> <div>0,4</div> <div>0,4</div> <div>0,4</div> <div>0,4</div> <div>0,4</div> <div>0,4</div> <div>0,4</div> <div>0,4</div> <div>0,4</div> <div>0,4</div> <div>0,4</div>	<div>Sampling plan according to ISO 2859 part. 1 – 1st Level inspection, single sampling plan, normal inspection.</div>
2	<div>1. *Black point on half case > 0,2 mm².</div> <div>2. Scratches on plastic components.</div>	<div>1,5</div> <div>1,5</div>	

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

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

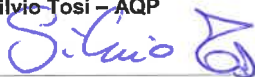
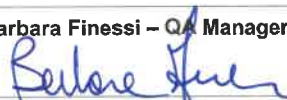
This material specification describes the properties of product above indicated.

This document contains general requirements, material description, drawing references, defect specification, biological material requirements.

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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)
02/12/2022	03	-Add product characteristics : Full-scale pressure 0.13bar and weld integrity 6bar -Update to Mod.984c rev.5	Silvio Tosi – AQP	Barbara Finessi – QA Manager
07/07/2023	04	_ Review Regulatory Documentation Required: add % DOTE and DEPH	Silvio Tosi – AQP 	Barbara Finessi – QA Manager 

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.