



PRODUCT SPECIFICATION

Product PN	TP100ACOG002AA00	Mod. 984
Description	Transducer Protector DEHP FREE	Rev. 00

Transducer Protector 0,2µm



PART DESCRIPTION	Transducer Protector Compatible for use with ISO 594-1/-2 connectors
MATERIALS	Membrane: Hydrophobic and Haemophobic PVDF 0,2 micron Height 15,5 mm Housing: PVC COLORITE AZURE Range Resistant DEHP FREE
PRODUCT CHARACTERISTICS	Weight : 2,1 gr Total Height : 23,4 mm
INSTRUCTIONS - WARNINGS	Keep note that part is made of elastic deformable material. Dimensions of the part will change under deformation. This fact doesn't jeopardize the functionality of the part. Flow area 144 mm ² .
STERILIZATION	EtO compatible [Max 50°C] Gamma Irradiation compatible [25 KGy]
BIOLOGICAL REQUIREMENTS	Test performed in compliance with UNI EN ISO 10993-1 and/or USP class VI All materials are DEHP free, Latex free and BSE/TSE free Test report available at GVS premises.
PACKAGING AND LABELLING	2.000 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 digit 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 by system, on each document of transport together with the complete traceability number of the goods. The Quality management system is in compliance with ISO 9001, ISO 13485:2003, ISO/TS 16949.
DRAWING	The attached drawing is part of this material specification and must not be duplicated or made accessible to a third party without prior consent.



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VISUAL REQUIREMENTS

Visual acceptance requirements apply when inspected under below conditions:

Instrument inspection: with naked eye and lamp

Distance: of 340 -450 mm

Timings: 5 sec per unit

Acceptance Requirement			AQL	Sampling Plan
1	Incomplete plastic support		0,25	ISO 2859 part. 1 1 st Level
2	Membrane missed		0,25	
3	Membrane jutting outside the housings		0,25	
4	Double membrane		0,25	
5	Upper and bottom parts not well aligned / assembled		0,25	
6	Warped, cracked		0,25	
7	Dust and loose particles		0,25	
8	Scratches internal cones with plastic residuals		0,25	
9	Membrane with splice (Tape residual)		0,25	
10	*Loose contamination > 0,2 mm ²		0,25	
11	Internal deformation		2,5	
12	Burrs >0,3mm		2,5	
13	*Embedded black spots > 0,2 mm ²		2,5	
14	Jutting injection gate > 0,2 mm ²		2,5	
15	Scratches with no plastic residuals		2,5	

***According to Dirt Estimation Chart (Tappi Standard).**

PERFORMANCE REQUIREMENTS

Acceptance Requirement			AQL	Sampling Plan
1	Air Flow	>= 30 ml/min (Pressure 12 mbar)	0,1	ISO 2859 part. 1 1 st Level
2	Water Break Through	1 bar for 1 hour	0,1	
3	Air Leakage	1 bar /30 sec. Verify the presence of air bubbles from housing	0,1	
4	Burst Test	2 bar /15 sec	0,1	
5	Dimensional (see drawing)	Female cone and male cone	0,1	

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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REVISIONI / REVISIONS:

DATA /DATE	REV.	MODIFICA DA PRECEDENTE REVISIONE/ REASON FOR CHANGE	MODIFICATO DA / CHANGED BY (name /function and signature)	APPROVATO DA/APPROVED BY (name /function and signature)
13/11/2013	00	First issue	Isabella Frignani Quality Assurance Process- Product	Isabella Frignani Quality Assurance Process- Product 

Customer Approval:

We accept this material specification as a part of the agreed terms of delivery

Date _____ Signature _____
(Company, Name, Function, Signature)

(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.