PRODUCT SPECIFICATION

Product PN	**TA156ATEKG050B00**	☐ PRELIMINARY ☐ R&D RELEASED ☑ RELEASED	Mod. 984c Rev. 05
Description	Bacterial Air Vent made whit 5 µm PVDF/PET Haemophobic/Hydrophobic Membrane		

Bacterial Air Vent

PRODUCT DESCRIPTION	Detailed description of the product: *Bacterial Air Vent made whit 5.0µm PVDF/PET Haemophobic/Hydrophobic Membrane.
INTENDED USE / APPLICATION	Air Vent for infusion set
MATERIALS	

P/N	Housing material	Filter media	COLOR
TA156ATEKG050B00	ABS	5.0 pore size PVDF/PET Haemophobic/ hydrophobic membrane	White

For raw materials used to produce components, Regulatory Documentation Required:
raw material membrane:
Test performed in compliance with USP class VI and/or ISO 10993-1.
raw material granule:

Regulatory Documentation Required:

- ☑ Rohs, directive 2002/95/CE
- ☑ BSE/TSE, directive 2003/32/CE
- ☑ DEHP plasticizer Free and latex free
- ☑ Reach 1907/2006/CE (hazardous substances regulation)
- ☑ Latex free
- ☑ Conflict minerals
- ☑ BPA and phthalates Free

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PRODUCT CHARACTERISTICS	**Dimensions:** Total height: 11,70 mm Total width: 9,80 mm Outside diameter (assembling side): 8,20 mm Internal diameter (assembling side): 6,33 mm
STERILIZATION	☑ EtO; ☑ Gamma (Max 25kGy);
PRODUCT SHELF LIFE	5 years
PACKAGING AND LABELLING	50.000 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: - 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 .
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:
Magnification: None
Light type: naked eye + lamp
Timing: 5 sec per unit
Distance: 30-45 cm

	cceptance Requirement	AQL	Sampling Plan
1	Plastic support incomplete	0,1	Sampling plan according to ISO 2859 part. 1 – 1st Level inspection, single sampling plan, normal inspection.
2	Deformations/squeezed parts	0,1	
3	Porosities, shrinkages	0,1	
4	Partially or totally missing membrane	0,1	
5	Double membrane	0,1	
6	Broken membrane	0,1	
7	Squeezed membrane	0,1	
8	Plastic infiltration > 0.2mm of membrane surface	0,1	
9	Membrane residual on the part	0,1	
10	Bubbles	0,1	
11	Dirty, grease on the part	0,1	
12	Rust on the part	0,1	
13	Flashes > 0,4 mm	1	
14	Plastic infiltration ≤ 0.2mm of membrane surface	1	
15	Threads	1	
16	Jutting injection gate > 0,2 mm	1	
17	*Embedded particulate matter > 0,1 mm^2	1,5	
18	Not uniform coloring/streaks	1,5	
19	Scrapes	1,5	
20	Embedded or loosing dirt not compromising the functionality of the part	1,5	
21	Loose contamination > 0,1 mm^2	1,5	

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DIMENSIONAL REQUIREMENTS

Acceptance Requirement	Value of reference	AQL	Sampling Plan
Internal diameter	6,33±0.05mm gauge go/no go	0,1	Sampling plan according to ISO 2859 part. 1 – S3 Special inspection level, single sampling plan, normal inspection.

PERFORMANCE REQUIREMENTS

Functional Testing		AQL	Sampling Plan
Air flow	≥ 70 cc/min (Pressure 10 mbar)	0,1	Sampling plan according to ISO 2859 part. 1 – 1st Level inspection, single sampling plan, normal inspection.
Water Break Through	0.08bar for 1 min	1	

***Note:** WBT test method, ramped pressure from 0 to 0.08bar in 10 seconds.

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)
09/06/2021	00	First issue	**Project Manager** Fausto Lentini	**Director Quality Assurance** Tiziana Landi

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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.