PRODUCT SPECIFICATION

Product PN	**RS201AEAS9W02A01**
Description	**IV Express 0.2 µm PES IV vented adult filter Female Luer lock / Male tube Ø3,3mm (Ø0.13”)**

Mod. 984

Rev. 02

IV Express TM
Adult vented filter

PRODUCT DESCRIPTION	IV Express™ is a non-sterile, non-toxic, self venting, single use, 96 hour filtration device with a 0.2 µm hydrophilic PES membrane and a 0.1 µm hydrophobic PVDF vent in a co-polyester housing. The connections are female luer lock inlet and male tube outlet. The product is provided in bulk packs for further manufacturing, processing, or repackaging
INTENDED USE / APPLICATION	The filter is designed for use in filtration of intravenous or other aqueous solutions for removal of particles larger than 0.2 µm
MATERIALS	**Housings (sleeve, core, vent screen):** Copolyester. **Filter media:** 0.2 µm Polyethersulfone hydrophilic filter membrane. **Vent:** 0.1 µm PVDF hydrophobic vent membrane. **Regulatory Documentation for raw materials** ☒Biocompatibility according ISO 10993-1 or USP Class VI ☒Rohs, directive 2002/95/CE ☒BSE/TSE, directive 2003/32/CE ☒DEHP plasticizer Free and latex free ☒Reach 1907/2006/CE (hazardous substances regulation) ☒Dir. 67/548/CE and Reg. 1272/2008/CE (medical sector dangerous substances) ☒Conflict minerals
PRODUCT CHARACTERISTIC	**Physical/Mechanical:** **Dimensions:** Length: 67 mm (2.63”) inlet to outlet / Body diameter: Ø17 mm (Ø0.67”) **Interfaces (ex: Input/Output connectors):** Inlet Female Luer lock connector in accordance to ISO80369-7 Outlet male tube adapter Ø3.3 mm (Ø0.13”) outer diameter – 6.5 mm (0.257”) length **Max Operating temperature:** 55 °C **Chemical:** It is not recommended to use any kind of disinfectant in direct contact with the filter housings. For more details, please contact GVS SpA. **Biological:** **Pyrogenicity:** ≤ 0.25 EU/ml using the LAL test method **Functional:** **Max operating pressure:** 3.1 bar (45 psig) for 60 sec **Liquid Flow Rate:** ≥ 30 ml/min at 80 cm (31.5 inch) water head height **Bubble Point Pressure:** ≥ 3.1 bar (45 psig) for 60 sec **Priming Volume:** ≤ 3 ml **Bacterial Retention:** Brevundimonas diminuta ≥ 7 log. red. value **Other:** For more info, please contact GVS SpA

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INSTRUCTIONS **WARNINGS**	Self priming IV filters. After the priming the filter can stay in any position. Filter for medical use, to be assembled into clean room. Remove the external bag before planting into a clean room. Handle with care. Cyclohexanone for gluing is recommended. Nevertheless, if PES hydrophilic membrane comes in contact with cycloexanone and its fumes, membrane breaks down. Usage with electric/mechanical pumps - When using filters with any pump model, always arrange pump section above the filter and preferably keep at least 50cm between pump section and filter inlet connector. Do not use for blood delivery, the filter clogs with whole blood or red blood cells.
STERILIZATION	☒ EtO; ☒ Gamma; gamma irradiation (Max 25 kGy)
BIOLOGICAL REQUIREMENTS	Assembly compatible with ISO 10993-1 Externally Communicating Device (Blood Path, Indirect). All materials USP class VI. All materials DEHP free. All materials Latex free.
PACKAGING AND LABELLING	**Packaging :** Filters shall be packaged in bulk using a double polybag and a double wall corrugated box carton. Each polybag shall be closed to prevent contamination. 1.000 filters packed in two PE bags. Bags are separately sealed. 2 bags per box. **Labelling**: ☒ Standard; ☐ Customer specific: Each box carton shall be labelled with the product part number and lot number. Box labels: 1. Product label: Product name: IV Express, Part Number, Lot Number, Quantity. Different lots of goods in one shipment are packed in a manner to prevent mix-ups. Different lots in one box are not allowed.
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, 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 written GVS SpA consent.

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VISUAL REQUIREMENTS

Visual acceptance requirements apply when inspected under below conditions:

Magnification: unaided eye, approximately 45 cm (18”) from eye
Illumination: 1000 ± 200 lx or equivalent
Light type: Fluorescent
Timings: 4 sec per unit

	Acceptance Requirement	AQL	Sampling Plan
1	No open weld line, holes on surface, short shots, splits and/or cracks	0.15	ISO 2859 part 1 1st level insp.
2	No flow lines or sinks on the inside and outside diameter that may contribute to channel leaks in the following areas: - Female Luer ID - Solvent Bond Areas : Adjacent to female luer (5.6 mm / 0.222” length) ID : Adjacent to housing body (6.5 mm / 0.265” length) OD	0.15	
3	No missing components	0.15	
4	No improperly sealed membrane	0.15	
5	No broken inlet or outlet	0.15	
6	No blockage in inlet, outlet or vent hole ports	0.15	
7	No visible loose particulate matter downstream of filter membrane	0.15	
8	No evidence of moisture. Assembly must be dry inside and out	0.15	
9	No excess flash greater than 0.030”	0.4	
10	No bubbles, splay and/or weld marks	0.4	
11	No embedded material > 0.20 mm² (Tappi Standard)	0.4	
12	No more than 3 embedded material < 0.20 mm² (Tappi Standard)	0.4	
13	No loose foreign particulate upstream of the filter	0.4	
14	No over or under welding	0.4	
15	No grease, dirt or discoloration in the filter assembly. **Note**: As a result of the heat staking process, some translucent areas could be created at the filter membrane seals. These are acceptable.	1.0	

PERFORMANCE REQUIREMENTS

	Acceptance Requirement		AQL	Sampling Plan
1	Filter Forward Pressure Integrity – Bubble point test.	≥ 3.1 bar (45 psig) for 60 sec	0,1%	ISO2859-1 Level S-4
2	Housing Pressure Integrity	≥ 3.1 bar (45 psig) for 60 sec	0,1%	ISO2859-1 Level S-4
3	Luer Leakage	≥ 3.1 bar (45 psig) for 30 sec	0,4%	ISO2859-1 Level S-3
4	Prime Test	≤ 15 sec	0,4%	ISO2859-1 Level S-3
5	Gravity Flow Rate	≥ 30 ml/min at 80 cm (31,5”) water head height	0,4%	ISO2859-1 Level S-3
6	Female Luer Bending Stress Force	≥ 6.8 kg (15 lbf)	1,0%	ISO2859-1 Level S-2
7	Outlet Bending Stress Force	≥ 3.2 kg (7 lbf)	1,0%	ISO2859-1 Level S-2
8	Maximum Particle Load	≤ 100 Particles ≥ 10 µm per device	1,5%	ISO2859-1 Level S-1
9	Bioburden Count	Maximum 50 micro organisms per device	-	-
10	Bacterial Endotoxin	≤ 20 EU per device	-	-

Control Note:
Customers who want to clarify requirements where judgmental differences may develop between the Customer and GVS SpA may submit limit samples for GVS SpA approval. If limits have not been established and approved, best judgement by GVS SpA Quality Assurance will apply.

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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)
15/05/2015	00	First issue	Enrico Colombo / Engineering Project Responsible	Barbara Finessi / QA Product & Process
21/06/2018	01	Inlet Female Luer Lock connector in accordance to ISO 80369-7	Enrico Colombo / Engineering Project Responsible	Barbara Finessi / QA Product & Process

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.