PRODUCT SPECIFICATION

CE 0051

Product PN	GMD022A00S - GMD023A00S - GMD024A00S GMD025A00S - GMD026A00S - GMD027A00S	Mod. 984e-ext
Description	Speedflow® IV filter Baby 0.2/0.2+/1.2/5 µm Non-Vented	Rev. 07

Speedflow® IV filter Baby 0.2/0.2+/1.2/5 µm Non-Vented



PRODUCT DESCRIPTION	Non-vented filter for infusion and anaesthesia. The device is sterile and can be used in combination with an infusion set or an infusion device (pump or syringe). The connections are a female luer lock with vented cap inlet and a rotating male luer lock with vented cap outlet, compliant with ISO 80369-7. The device is provided with a non-vented Speedflow® Neonatal filter, with a hydrophilic PES membrane with 0.2/0.2+/1.2/5.0 µm pore size for particles retention and a hydrophobic PTFE membrane with 0.03 µm pore size. The filter size (LxWxH) is 15.3x62x9.6 mm.
CONFIGURATIONS	**GMD022A00S** 0.2+ (positively charged) µm **GMD023A00S** 0.2 µm **GMD024A00S** 0.2 µm amber color **GMD025A00S** 1.2 µm **GMD026A00S** 1.2 µm amber color **GMD027A00S** 5.0 µm
MANUFACTURER NAME	**GVS SpA** Via Roma, 50 40069 Zola Predosa (BO) – ITALY Phone: +39.051.6176311 – Fax: +39.051.6176200 e-mail: gvs@gvs.com – website: www.gvs.com
INTENDED USE / APPLICATION	Infusion of Drugs (including chemotherapy), Anesthetics, Nutritional Solutions and Saline Solutions. The amber version is designed for the administration of photosensitive drugs. The filter can be connected via Luer Locks to all commercially available infusion administration sets compliant with ISO 80369-7. The device is intended to retain different particles depending on its filter pore size: ▪ 0.2 µm filter is intended specifically to retain particles and bacteria, ▪ 1.2 µm filter is intended specifically to retain fungi and microorganisms, ▪ 0.2+ µm filter is intended specifically to retain particles, bacteria and endotoxins, ▪ 5.0 µm filter is intended specifically to retain particles. The device is a single-use device that can be used applications that last: ▪ Devices with 0.2 µm filter: up to 96 hours; ▪ Devices with 1.2 µm filter: up to 24 hours; ▪ Devices with 0.2+ µm filter: up to 120 hours. The device has to be disposed after each therapy. Devices with 0.2/0.2+ µm filter cannot be used for infusion of hyper alimentation liquids, lipids, blood and/or blood derivatives. Devices with 1.2 µm filter cannot be used for infusion of blood and/or blood derivatives. Devices with 5.0 µm filter cannot be used for infusion of blood and/or blood derivatives. If bacterial or fungi retention is needed, do not use the filters with 5.0 µm pore size without filtration. The device should only be supervised and used by qualified healthcare personnel.
CLASS OF THE PRODUCT	Class IIa – sterile – single use Rule 3 Annex VIII Regulation (UE) 2017/745
REGISTRATION NUMBERS	**Italian national database:** **GMD022A00S 3087023/R** **GMD023A00S 3087026/R** **GMD024A00S 3087027/R** **GMD025A00S 3087028/R**

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	GMD026A00S **3087030/R** **GMD027A00S** **3087031/R**
EMDN	**A04010101** WITHDRAWL AND ADMINISTRATION FILTERS (0.2-1.2 MICRONS) **A04010102** ASPIRATION AND TRANSFER FILTERS (>= 5 MICRONS)
MATERIALS	**Filter media**: PES **Filter Housing**: PP, MABS **Caps:** HDPE **Regulatory Compliance** ▪ Biocompatibility according to ISO 10993-1 ▪ Rohs directive 2011/65/UE ▪ DEHP plasticizer Free ▪ Latex free ▪ Reach 1907/2006/CE (hazardous substances regulation) ▪ Reg. 1272/2008/CE (classification, labelling and packaging of substances and mixtures)
PRODUCT CHARACTERISTIC	**Physical/Mechanical:** **Dimensions (LxWxH):** 15.3x62x9.6 mm **Total internal volume of the set:** < 0.35 ml **Weight:** 2.75 g **Input/output connectors:** Female luer lock with vented cap inlet and rotating male luer lock with vented cap outlet, compliant with ISO 80369-7 **Operating temperature Range:** From 5 °C to 40 °C **Storage temperature Range:** From 0 °C to 40 °C **Maximum applicable pressure:** 8.0 bar **Flow Rate:** 0.2 µm: ≥ 4 ml/min @ 80 cm (31.5 in) water head pressure 0.2 µm+: ≥ 3.5 ml/min @ 80 cm (31.5 in) water head pressure 1.2 µm: ≥ 30 ml/min @ 80 cm (31.5 in) water head pressure 5.0 µm: ≥ 55 ml/min @ 80 cm (31.5 in) water head pressure **Bubble point:** 0.2 µm: 3.7 ÷ 4.8 bar 0.2+ µm: 3.7 ÷ 4.8 bar 1.2 µm: 0.7 ÷ 1.0 bar 5.0 µm: 0.15 ÷ 0.3 bar **Biological:** **Biocompatibility:** Compliant with ISO 10993-1 **Features:** **Type of administration:** gravity / pressure **Duration of the application:** 0.2 µm up to 96 hours 1.2 µm up to 24 hours 0.2+ µm up to 120 hours **Filter:** Baby Neonatal 0.2+/0.2/1.2/5µm non-vented **Filter pore size:** 0.2 µm **Filter internal volume:** < 0.35 ml **Filter media:** hydrophilic PES membrane
PRODUCT SHELF LIFE	5 years.
STERILIZATION	**Sterile:** Yes –Ethylene Oxide (EtO) **Suitable for Sterilization/Re-sterilization:** No
APPLICABLE STANDARDS AND REGULATIONS	**Product Certification:** CE mark **Applicable Standards and Technical Regulations:** EN 556-1 Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices EN ISO 8536-4 Infusion equipment for medical use — Part 4: Infusion sets for single use, gravity feed

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	EN ISO 8536-9	Infusion equipment for medical use — Part 9: Fluid lines for single use with pressure infusion equipment
	EN ISO 8536-11	Infusion equipment for medical use — Part 11: Infusion filters for single use with pressure infusion equipment
	EN ISO 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
	EN ISO 10993-4	Biological evaluation of medical devices — Part 4: Selection of tests for interactions with blood
	EN ISO 10993-5	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
	EN ISO 10993-7	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
	EN ISO 10993-10	Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization
	EN ISO 10993-11	Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity
	EN ISO 10993-18	Biological evaluation of medical devices - Part 18: Chemical characterization of materials
	EN ISO 10993-23	Biological evaluation of medical devices — Part 23: Tests for irritation
	EN ISO 11135	Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices
	EN ISO 11607-1	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
	EN ISO 11607-2	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
	EN ISO 13485	Medical devices - Quality management systems - Requirements for regulatory purposes
	EN ISO 14971	Medical devices - Application of risk management to medical devices
	EN ISO 15223-1	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
	EN ISO 20417	Medical devices - Information to be supplied by the manufacturer
	IEC 62366-1	Medical devices – Part 1: Application of usability engineering to medical devices
	EN ISO 80369-1	Small-bore connectors for liquids and gases in healthcare applications — Part 1: General requirements
	EN ISO 80369-7	Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications
	EN ISO 80369-20	Small-bore connectors for liquids and gases in healthcare applications — Part 20: Common test methods

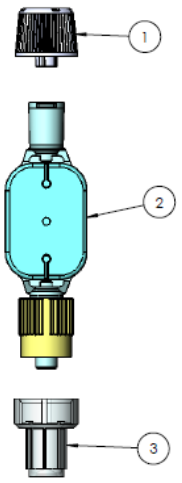
INSTRUCTIONS FOR USE	**Available languages:**	English / Italian / German / French / Spanish / Hungarian / Romanian
PACKAGING	**Primary Packaging:**	Devices are individually packed and label in medical paper pouches. Pouch Size: 100 X 145 mm
	Secondary Packaging:	Pouches are placed inside a microperforated bag.
	Tertiary Packaging:	Carton Box. Box Size: 60 x 40 x 20 cm Box Weight: 4 kg Devices per box: 400
CERTIFICATIONS	**ISO 9001:2015** **ISO 13485:2016** **CE Certificate (2017/745/UE)**	

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DRAWING



ID	Description
1	Vented male rotating cap for female Luer Lock
2	EPI-Baby filter Neonatal 0.2 µm non-vented
3	Vented protecting cap for rotating male Luer Lock

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REVISIONS AND APPROVALS:

DATE	REV.	REASON FOR CHANGE	ISSUED BY: (name/function/signature)	VERIFIED BY: (name/function/signature)	APPROVED BY: (name/function/signature)
26/10/2026	00	First emission	Antonio Berti Project Manager 	Barbara Palmieri RA Specialist  Enrico Salvarani Head of Product Development 	Barbara Finessi QA Manager  Luca Zanini VP MedTech Division 