PRODUCT SPECIFICATION

CE 0051

Product PN	**GMD019A00S**	**Mod. 984e-ext**
Description	**EPI-Baby IV Filter Neonatal 0.2 µm Luer Lock**	**Rev. 07**

EPI-Baby IV Filter Neonatal 0.2 µm with Luer Lock

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 EPI-Baby Neonatal filter, with an hydrophilic PES membrane with 0.2 µm pore size for particles retention. The filter size (LxWxH) is 15.3x62x9.6 mm.
MANUFACTURER NAME	**GVS SpA** Via Roma, 50 40069 Zola Predosa (BO) – ITALY Phone: +39.051.6176311 – Fax: +39.051.6176200 e-mail: gvs@gvs.it – website: www.gvs.com
INTENDED USE / APPLICATION	Infusion of Drugs (including chemotherapy), Anesthetics, Nutritional Solutions and Saline Solutions. The filter can be connected via Luer Locks to all commercially available infusion administration sets compliant with ISO 80369-7. The filter can be used in combination with an infusion set or an infusion device (pump or syringe). The filter is intended specifically to eliminate air bubbles and to retain particles and bacteria (0.2 µm), The filter can be used for applications that last up to 96 hours. The device has to be disposed after each therapy. The device should only be supervised and used by qualified healthcare personnel. The filter can't be used for infusion of hyper alimentation liquids, lipids, blood and/or blood derivatives.
CLASS OF THE PRODUCT	Class IIa – sterile – single use Rule 3 Annex VIII Regulation (UE) 2017/745
REGISTRATION NUMBERS	**Italian national database:** **GMD019A00S** 2439204
EMDN	**A04010101** WITHDRAWL AND ADMINISTRATION FILTERS (0.2-1.2 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

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	Maximum applicable pressure:	8.0 bar
	Flow Rate:	≥ 4 ml/min @ 80 cm (31.5 in) water head pressure
	Bubble point:	3.7 ÷ 4.8 bar
	Chemical:	
	Compatibility to solvents:	Isopropyl Alcohol
	Biological:	
	Biocompatibility:	Compliant with ISO 10993-1
	Features:	
	Type of administration:	gravity / pressure
	Duration of the application:	up to 96 hours
	Filter:	EPI-Baby Neonatal 0.2 µm 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 Resterilization:	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
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

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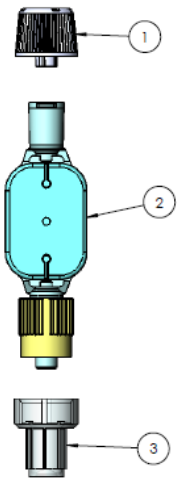
INSTRUCTIONS FOR USE	EN ISO 80369-7	Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications
	EN ISO 80369-20	Small-bore connectors for liquids and gases in healthcare applications — Part 20: Common test methods
	Available 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)**	
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

REVISIONS AND APPROVALS:

DATE	REV.	REASON FOR CHANGE	ISSUED BY: (name/function/signature)	VERIFIED BY: (name/function/signature)	APPROVED BY: (name/function/signature)
14/02/2025	02	Added Hungarian and Romanian translations on labels and IFU	Barbara Palmieri RA Specialist	Barbara Finessi QA Manage	Luca Zanini VP Healthcare and Lifesience