

Product PN GMD020A00S

Description EPI-MAX IV Filter Adult 0,2 µm NRfit

Mod. 984e-ext

Rev. 07

EPI-MAX IV Filter Adult 0,2 µm NRfit



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). Filtration device with a hydrophilic PES membrane (0.2 µm) and a reinforced MBS housing. The connections are female neuraxial lock inlet and rotating male neuraxial lock outlet, in compliance with ISO 80369-6, with vented protective caps. Rotating nut is available in yellow colour.		
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 - www.gvs.com		
INTENDED USE / APPLICATION	Infusion of Drugs (including chemotherapy), Anesthetics, Nutritional Solutions and Saline Solutions. Specific for Neuraxial applications. Resistant to isopropyl alcohol. The filter can be connected via neuraxial lock connectors to all commercially available infusion administration sets compliant with ISO80369-6. The filter can be used in combination with an infusion set or an infusion device (pump or syringe). The device with 0.2 µm filter is intended specifically to eliminate air bubbles and to retain particles and bacteria. The device is a single-use device that can be used applications that last up to 96 hours. The device has to be disposed after each therapy. Devices with 0.2 µm filter cannot be used for infusion of hyper alimentation liquids, lipids, blood and/or blood derivatives. The device should only be supervised and used by qualified healthcare personnel.		
CLASS OF THE PRODUCT	Single use Medical device – Class IIa sterile. Rule 3 attachment VIII Regulation (UE) 2017/745		
REGISTRATION NUMBERS	Italian national database: 2995649/R		
EMDN	A04010101 WITHDRAWAL AND ADMINISTRATION FILTERS (0.2-1.2 MICRONS)		
MATERIALS	Filter media: PES Filter Housing: PP, (MBS) MED2 Color: Neutral Housing with yellow rotating nut Caps: HDPE, ABS 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): 30x76,9x4 mm Total internal volume: 1,2 ml Weight: 7,08 g Input/output connectors: Female neuraxial lock inlet and rotating male neuraxial lock outlet, in compliance with ISO 80369-6, with vented protective caps.		



PRODUCT SPECIFICATION



Product PN GMD020A00S

Mod. 984e-
ext

Description EPI-MAX IV Filter Adult 0,2 µm NRfit

Rev. 07

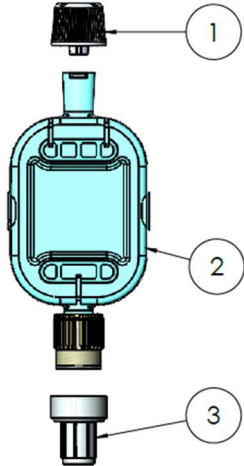
	Operating temperature Range: From 5 °C to 40 °C Storage temperature Range: From 0 °C to 40 °C Maximum applicable pressure: 8.0 bar Flow Rate: ≥ 15 ml/min @ 80 cm (31.5 in) water head pressure Bubble point: 3.7 ÷ 4,8 bar Chemical: Compatibility to solvents: Isopropyl Alcohol Biological: Biocompatibility: Compliant with ISO 10993-1 Features: Type of administration: gravity / pressure Duration of the application: 0.2 µm up to 96 hours Filter: EPI-MAX Adult 0.2 µm non-vented Filter pore size: 0.2 µm 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: <table><tr><td>EN 556-1</td><td>Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices</td></tr><tr><td>EN ISO 8536-4</td><td>Infusion equipment for medical use — Part 4: Infusion sets for single use, gravity feed</td></tr><tr><td>EN ISO 8536-9</td><td>Infusion equipment for medical use — Part 9: Fluid lines for single use with pressure infusion equipment</td></tr><tr><td>EN ISO 8536-11</td><td>Infusion equipment for medical use — Part 11: Infusion filters for single use with pressure infusion equipment</td></tr><tr><td>EN ISO 10993-1</td><td>Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process</td></tr><tr><td>EN ISO 10993-4</td><td>Biological evaluation of medical devices — Part 4: Selection of tests for interactions with blood</td></tr><tr><td>EN ISO 10993-5</td><td>Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity</td></tr><tr><td>EN ISO 10993-7</td><td>Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals</td></tr><tr><td>EN ISO 10993-10</td><td>Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization</td></tr><tr><td>EN ISO 10993-11</td><td>Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity</td></tr><tr><td>EN ISO 10993-18</td><td>Biological evaluation of medical devices - Part 18: Chemical characterization of materials</td></tr><tr><td>EN ISO 10993-23</td><td>Biological evaluation of medical devices — Part 23: Tests for irritation</td></tr><tr><td>EN ISO 11135</td><td>Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices</td></tr><tr><td>EN ISO 11607-1</td><td>Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems</td></tr><tr><td>EN ISO 11607-2</td><td>Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes</td></tr><tr><td>EN ISO 13485</td><td>Medical devices - Quality management systems - Requirements for regulatory purposes</td></tr><tr><td>EN ISO 14971</td><td>Medical devices - Application of risk management to medical devices</td></tr><tr><td>EN ISO 15223-1</td><td>Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements</td></tr><tr><td>EN ISO 20417</td><td>Medical devices - Information to be supplied by the manufacturer</td></tr><tr><td>IEC 62366-1</td><td>Medical devices – Part 1: Application of usability engineering to medical devices</td></tr></table>	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 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																																								

Product PN GMD020A00S

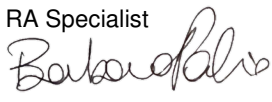
Mod. 984e-
ext

Description EPI-MAX IV Filter Adult 0,2 µm NRfit

Rev. 07

	EN ISO 80369-1 Small-bore connectors for liquids and gases in healthcare applications — Part 1: General requirements EN ISO 80369-6 Small-bore connectors for liquids and gases in healthcare applications — Part 6: Connectors for neuraxial 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: 3 Kg Devices per box: 300								
CERTIFICATE OF COMPLIANCE	ISO 9001:2015 ISO 13485:2016 CE Certificate (2017/745/UE)								
DRAWING	 <table border="1"> <thead> <tr> <th>ID</th><th>Description</th></tr> </thead> <tbody> <tr> <td>1</td><td>NRFit non-vented Male cap for Female Luer Lock</td></tr> <tr> <td>2</td><td>IV Epidural filter 0.2 µm NRfit with yellow ring</td></tr> <tr> <td>3</td><td>Protecting cap for Rotating Male Luer Lock</td></tr> </tbody> </table>	ID	Description	1	NRFit non-vented Male cap for Female Luer Lock	2	IV Epidural filter 0.2 µm NRfit with yellow ring	3	Protecting cap for Rotating Male Luer Lock
ID	Description								
1	NRFit non-vented Male cap for Female Luer Lock								
2	IV Epidural filter 0.2 µm NRfit with yellow ring								
3	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)
09/04/2026	00	First Emission	Elsa Caruso RP 	Barbara Palmieri RA Specialist  Enrico Salvarani RPROG 	Barbara Finessi QA Manager  Luca Zanini VP Healthcare and Lifesience 