# PRODUCT SPECIFICATION

CE 0051

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|---|---|
| **Product PN** GMD028A00S | Mod. 984e-ext<br>Rev. 07 |
| **Description** **EPI-MAX IV Filter Adult 0,2 µm Luer Lock** | |

## EPI-MAX IV Filter Adult 0.2 µm Luer Lock




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| **PRODUCT DESCRIPTION** | Non-vented filter for infusion and anaesthesia.<br>The device is sterile and can be used in combination with an infusion set or an infusion device (pump or syringe).<br>Filtration device with a hydrophilic PES membrane (0.2 µm) and a reinforced MBS housing.<br>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.<br>Rotating nut is available in transparent colour.<br>The filter size (LxWxH) is 30x67x7.2 mm. |
| **CONFIGURATIONS** | **GMD028A00S** 0.2 µm |
| **MANUFACTURER NAME** | **GVS SpA**<br>Via Roma, 50<br>40069 Zola Predosa (BO) – ITALY<br>Phone: +39.051.6176311 – Fax: +39.051.6176200<br>e-mail: gvs@gvs.com – website: www.gvs.com |
| **INTENDED USE / APPLICATION** | Infusion of Drugs (including chemotherapy), Anesthetics, Nutritional Solutions and Saline Solutions.<br>Specific for Neuraxial applications. Resistant to isopropyl alcohol.<br>The filter can be connected via lock connectors to all commercially available infusion administration sets compliant with ISO 80369-7.<br>The filter can be used in combination with an infusion set or an infusion device (pump or syringe).<br>The device with 0.2 µm filter is intended specifically to retain particles and bacteria.<br>The device is a single-use device that can be used applications that last up to 96 hours.<br>The device has to be disposed after each therapy.<br>Devices with 0.2 µm filter cannot be used for infusion of hyper alimentation liquids, lipids, blood and/or blood derivatives.<br>The device should only be supervised and used by qualified healthcare personnel. |
| **CLASS OF THE PRODUCT** | Class IIa – sterile – single use<br>Rule 3 Annex VIII Regulation (UE) 2017/745 |
| **REGISTRATION NUMBERS** | **Italian national database:**<br>**GMD028A00S** **3086818/R** |
| **EMDN** | **A04010101** WITHDRAWL AND ADMINISTRATION FILTERS (0.2 MICRONS) |
| **MATERIALS** | **Filter media**: PES<br>**Filter Housing**: PP, MABS<br>**Caps:** HDPE<br><br>**Regulatory Compliance**<br>▪ Biocompatibility according to ISO 10993-1<br>▪ Rohs directive 2011/65/UE<br>▪ DEHP plasticizer Free<br>▪ Latex free<br>▪ Reach 1907/2006/CE (hazardous substances regulation)<br>▪ Reg. 1272/2008/CE (classification, labelling and packaging of substances and mixtures) |

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## PRODUCT CHARACTERISTIC

### Physical/Mechanical:

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| **Dimensions (LxWxH):** | 30x67x7.2 mm |
| **Total internal volume of the set:** | 1.2 ml |
| **Weight:** | 7.86 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: ≥ 15 ml/min @ 80 cm (31.5 in) water head pressure |
| **Bubble point:** | 0.2 µm: 3.7 ÷ 4,8 bar |

### Chemical:

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| **Compatibility to solvents:** | Isopropyl Alcohol |

### Biological:

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| **Biocompatibility:** | Compliant with ISO 10993-1 |

### Features:

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| **Type of administration:** | gravity / pressure |
| **Duration of the application:** | 0.2 µm up to 96 hours |
| **Filter:** | Speedflow® Adult 0.2 µm non-vented |
| **Filter pore size:** | 0.2 µm |
| **Filter internal volume:** | 1.2 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

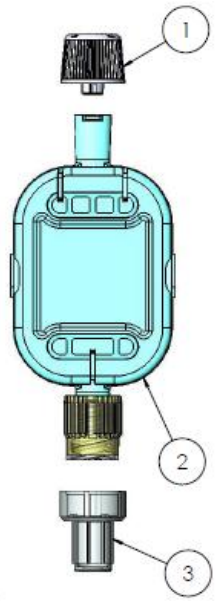
**Applicable Standards and Technical Regulations:**

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|---|---|
| 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 |

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|---|---|---|
| | 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 in: | English / Italian / German / French / Spanish / Hungarian / Romanian |
| **PACKAGING** | **Primary Packaging:** | Devices are individually packed and label in medical paper pouches.<br>Pouch Size: 100 X 145 mm |
| | **Secondary Packaging:** | Pouches are placed inside a microperforated bag. |
| | **Tertiary Packaging:** | Carton Box.<br>Box Size: 60 x 40 x 20 cm<br>Box Weight: 3 Kg<br>Devices per box: 300 |
| **CERTIFICATIONS** | **ISO 9001:2015**<br>**ISO 13485:2016**<br>**CE Certificate (2017/745/UE)** | |
| **DRAWING** |  | |

| ID | Description |
|---|---|
| 1 | Vented male rotating cap for female Luer Lock |
| 2 | Speedflow Adult 0.2 µm IV filter 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<br>Project Manager<br> | Barbara Palmieri<br>RA Specialist<br><br>Enrico Salvarani<br>Head of Product Development<br> | Barbara Finessi<br>QA Manager<br><br>Luca Zanini<br>VP MedTech Division<br> |