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| Product PN | GSS003A02S GSS003B02S GSS004A02S GSS004B02S | Mod. 984e-ext |
| Description | HI-FLO Extension Set Pediatric 0.2/1.2 µm with Y-Infusion connector | Rev. 07 |

HI-FLO Extension Set Pediatric with Filter and Y-injection



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| PRODUCT DESCRIPTION | <p>Infusion extension set for infusion for intravascular applications.</p> <p>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 male luer lock with cap/with ring and protective cap outlet, compliant with ISO 80369-7.</p> <p>The set is provided with a vented Speedflow® Pediatric filter, with an hydrophilic PES membrane with 0.2/1.2 µm pore size for particles retention and a hydrophobic PTFE membrane with 0,03 µm pore size.</p> <p>The set is provided with a y-injection site, for administration of additional drugs by means of a syringe using the same infusion line.</p> <p>The approximate total length of the set is 630 mm.</p> <p>The set includes the following components:</p> <ul style="list-style-type: none"> Female luer lock with vented cap inlet; Y-Injection point; Speedflow Pediatric 0.2/1.2 µm IV Filter; Slide clamp; Male luer lock with cap/with ring and protective cap outlet. | |
| CONFIGURATIONS | GSS003A02S GSS004A02S GSS003B02S GSS004B02S | 0.2 µm with male luer lock with cap outlet 1.2 µm with male luer lock with cap outlet 0.2 µm with male luer lock with ring and protective cap outlet 1.2 µm with male luer lock with ring and protective cap outlet |
| MANUFACTURER NAME | <p>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</p> | |
| INTENDED USE / APPLICATION | <p>Infusion of Drugs (including chemotherapy), Anesthetics, Nutritional Solutions and Saline Solutions for intravascular applications.</p> <p>The set can be connected via Luer Locks to all commercially available infusion administration sets compliant with ISO 80369-7.</p> <p>The set can be used either for gravity or in combination with an infusion set or an infusion device (pump or syringe). The set with 0.2 µm filter is intended specifically to eliminate air bubbles and to retain particles and bacteria, while the set with 1.2 µm filter is intended specifically to eliminate air bubbles and to retain fungi and microorganisms.</p> <p>The set is a single-use device that can be used applications that last:</p> <ul style="list-style-type: none"> Devices with 0.2 µm filter: up to 96 hours; Devices with 1.2 µm filter: up to 24 hours. <p>The set has to be disposed after each therapy.</p> <p>Sets with 0.2 µm filter cannot be used for infusion of hyper alimentation liquids, lipids, blood and/or blood derivatives.</p> <p>Sets with 1.2 µm filter cannot be used for infusion of blood and/or blood derivatives.</p> <p>The device should only be supervised and used by qualified healthcare personnel.</p> | |
| CLASS OF THE PRODUCT | <p>Class IIa – sterile – single use</p> <p>Rule 2 and 3 Annex VIII 2017/472/UE</p> | |



PRODUCT SPECIFICATION

CE 0051

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| REGISTRATION NUMBERS | Italian national database: GSS003A02S 2439335 GSS004A02S 2439336 GSS003B02S 2439339 GSS004B02S 2439340 | |
| EMDN | A03020101 | LOW PRESSURE EXTENSION LINES |
| MATERIALS | Filter media: PES Hydrophilic membrane / PTFE Hydrophobic membrane Filter housing: MBS Tubes: PVC (DEHP Free) Y-injection: SEBS / MABS Luer Lock: PVC / MABS Caps: HDPE Clamp: PP Regulatory Compliance: <ul style="list-style-type: none">▪ Biocompatibility according to ISO 10993-1▪ Rohs directive 2011/65/EU▪ 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 CHARACTERISTICS | Physical/Mechanical: Approximate total length: 630 mm Total internal volume of the set: 11 ml Weight: 13.1 g Input/output connectors: Female luer lock with vented cap inlet compliant with ISO 80369-7 'A' model: Male luer lock with cap outlet compliant with ISO 80369-7 'B' model: Male luer lock with ring and protective 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: 3.2 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 Speedflow Pediatric 0.2/1.2 µm vented Filter: Filter pore size: 0.2 µm Filter internal volume: < 1.3 ml Filter media: hydrophilic PES membrane and hydrophobic PTFE membrane Flow Regulator: No Drip Chamber: No Roller: No Y-injection site: Yes Clamp: Slide clamp Tubing: PVC tube – inner Ø 3.0 mm / outer Ø 4.1 mm | |
| PRODUCT SHELF LIFE | 5 years | |
| STERILIZATION | Sterile: Yes – EtO Suitable for Sterilization/Re-sterilization: No | |



PRODUCT SPECIFICATION

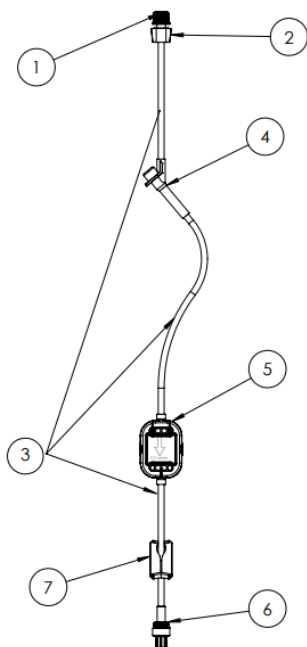


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| APPLICABLE STANDARDS AND REGULATIONS | Product Certification: | CE mark |
| | Applicable Standards and Technical Regulations: | |
| | EN 556-1 | Sterilization of medical devices — Requirements for medical devices to be designated "STERILE" — Part 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 |
| INSTRUCTIONS FOR USE PACKAGING | Available languages: | English / Italian / German / French / Spanish / Hungarian / Romanian |
| | Primary Packaging: | Devices are individually packed and label in medical paper bags. Bag Size: 130 X 200 mm |
| | Secondary Packaging: | Bags are placed inside a microperforated sack. |
| | Tertiary Packaging: | Carton Box. Box Size: 60 x 40 x 20 cm Box Weight: 2 Kg Devices per box: 100 |
| CERTIFICATIONS | ISO 9001:2015 ISO 13485:2016 CE Certificate (2017/745/UE) | |

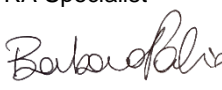

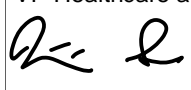
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DRAWING



| ID | Description |
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| 1 | Vented male rotating cap for female Luer Lock |
| 2 | Female Luer Lock connector Ø 4.1 mm |
| 3 | Tube 15 cm – inner Ø 3.0 mm / outer Ø 4.1 mm |
| 4 | Y-Injection site |
| 5 | '3' model: Speedflow Pediatric 0.2 µm IV filter '4' model: Speedflow Pediatric 1.2 µm IV filter |
| 6 | 'A' model: Male luer lock with cap 'B' model: Male luer lock with ring and protective cap |
| 7 | Slide Clamp |

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 | 03 | Added Hungarian and Romanian translations on labels and IFU | Barbara Palmieri RA Specialist  | Barbara Finessi QA Manage  | Luca Zanini VP Healthcare and Lifesience  |