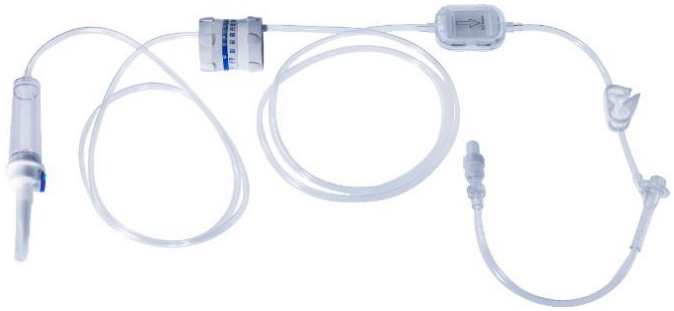
PRODUCT SPECIFICATION

CE 0051

Product PN GIS005A01S GIS006A01S	Mod. 984e-ext
Description HI-FLO IV Set Adult 0.2/1.2 µm Easydrop® double scale	Rev. 07

HI-FLO IV Set Adult with 0.2/1.2 µm Filter and Regulator



PRODUCT DESCRIPTION	Infusion set for infusion for intravascular applications. The device is sterile and is for gravity feed infusion only. The set has a vented IV drip chamber (20 drops/ml) and a male luer lock outlet with ring and protective cap, compliant with ISO 80369-7. The set is provided with a vented Speedflow® Adult 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. The set also includes a flow regulator Easydrop® double scale, to approximately regulate the flow rate. The set is provided with a y-injection site, for administration of additional drugs by means of a syringe using the same infusion line, and with a clamp. The approximate total length of the set is 2135 mm. The set includes the following components: ▪ Drip Chamber (20 drops/ml); ▪ Flow regulator Easydrop® double scale; ▪ Speedflow® Adult 0.2/1.2 µm IV Filter; ▪ Clamp; ▪ Y-Injection point; ▪ Male luer lock outlet with ring and protective cap.
CONFIGURATIONS	**GIS005A01S** 0.2 µm with Easydrop® double scale **GIS006A01S** 1.2 µm with Easydrop® double scale
MANUFACTURER NAME	**GVS S.p.A.** Via Roma, 50 – 40069 Zola Predosa (BO) – Italy Phone : +39.051.6176311 – Fax: +39.051.6176200 email: gvs@gvs.it – website: www.gvs.com
INTENDED USE / APPLICATION	Infusion of Drugs (including chemotherapy), Anesthetics, Nutritional Solutions and Saline Solutions for intravascular applications. The set can be connected via Luer Locks to all commercially available infusion administration sets compliant with ISO 80369-7. The set is for gravity feed infusion. 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. The set 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. The set has to be disposed after each therapy. Sets with 0.2 µm filter cannot be used for infusion of hyper alimentation liquids, lipids, blood and/or blood derivatives. Sets with 1.2 µm filter cannot be used for infusion of blood and/or blood derivatives. The device should only be supervised and used by qualified healthcare personnel.
CLASS OF THE PRODUCT	Class IIa – sterile – single use Rule 2 and 3 Annex VIII 2017/472/UE
EMDN	A03010102 INFUSION CONTROLLERS WITH FILTER (ALSO TRANSFUSION CONTROLLERS)
MATERIALS	**Filter media:** PES Hydrophilic membrane / PTFE Hydrophobic membrane **Filter housing:** MBS **Tubes:** PVC (DEHP Free) **Flow Regulator:** SEBS / ABS / Alkyl Polysiloxane **Drip Chamber:** ABS / PVC (DEHP Free) / LDPE / HDPE / PA6.6 / NY **Y-injection:** SEBS / MABS **Clamp:** PP / LDPE

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	Luer Lock: MABS / PP **Caps:** HDPE **Regulatory Compliance:** ▪ 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:** 2135 mm **Total internal volume of the set:** 34.1 ml **Weight (approx.):** 45 g **Input/output connectors:** Male luer lock outlet with ring and protective cap compliant with ISO 80369-7 **Operating temperature Range:** From 5 °C to 40 °C **Storage temperature Range:** From 0 °C to 40 °C **Biological:** **Biocompatibility:** Compliant with ISO 10993-1 **Features:** **Type of administration:** gravity **Duration of the application:** 0.2 µm up to 96 hours 1.2 µm up to 24 hours **Filter:** Speedflow Adult 0.2/1.2 µm vented **Filter pore size:** 0.2/1.2 µm **Filter internal volume:** < 2.4 ml **Filter media:** hydrophilic PES membrane and hydrophobic PTFE membrane **Flow Regulator:** Easydrop® double scale **Drip Chamber:** Yes – 20 drops / ml **Roller:** No **Y-injection site:** Yes **Clamp:** Yes **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
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 8536-11 — Infusion equipment for medical use — Part 11: Infusion filters for single use with pressure infusion equipment EN ISO 8536-13 — Infusion equipment for medical use — Part 13: Graduated flow regulators for single use with fluid contact EN ISO 8536-14 — Infusion equipment for medical use — Part 14: Clamps and flow regulators for transfusion and infusion equipment without fluid contact 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

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	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	**A**vailable languages: English / Italian / German / French / Spanish
PACKAGING	**Primary Packaging:** Devices are individually packed and label in medical paper bags. Bag Size: 150 X 250 mm **Secondary Packaging:** Bags are placed inside a microperforated sack. **Tertiary Packaging:** Carton Box. Box Size: 60 x 40 x 20 cm Box Weight: 4.4 Kg Devices per box: 70
CERTIFICATIONS	**ISO 9001:2015** **ISO 13485:2016** **CE Certificate (2017/745/UE)**

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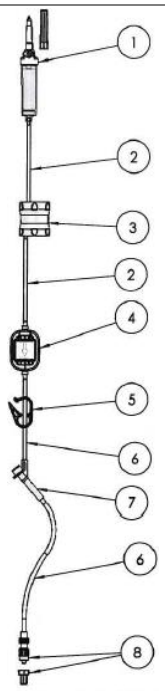
DRAWING



ID	Description
1	Drip Chamber 20 drops/ml
2	Tube 75 cm – inner Ø 3.0 mm / outer Ø 4.1 mm
3	Flow Regulator Easydrop® double scale
4	'1' model: Speedflow Adult 0.2 µm IV filter '2' model: Speedflow Adult 1.2 µm IV filter
5	Clamp
6	Tube 15 cm – inner Ø 3.0 mm / outer Ø 4.1 mm
7	Y-Injection site
8	Male Luer Lock with ring and protective cap Ø 4.1 mm

REVISIONS AND APPROVALS:

DATE	REV.	REASON FOR CHANGE	ISSUED BY: (name/function/signature)	VERIFIED BY: (name/function/signature)	APPROVED BY: (name/function/signature)
26/02/2023	00	First issue	Barbara Palmieri RA Specialist	Barbara Finessi QA Manage	Luca Zanini VP Healthcare and Lifesience