PRODUCT SPECIFICATION

CE

Product PN GIS013M02S	Mod. 984e-ext
Description HI-FLO IV Set Hybrid Easydrop® double scale	Rev. 07

HI-FLO IV Set with Regulator and y-injection

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 with rotating nut and female luer filter outlet, compliant with ISO 80369-7. The set is provided with 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 2204 mm. The set includes the following components: ▪ Drip Chamber (20 drops/ml); ▪ Clamp; ▪ Flow regulator Easydrop® double scale; ▪ Y-Injection point; ▪ Male luer lock with rotating nut and female luer filter outlet.
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 is a single-use device and has to be disposed after each therapy. The device should only be supervised and used by qualified healthcare personnel.
CLASS OF THE PRODUCT	Class Is – sterile – single use Rule 2 Annex VIII 2017/472/UE
EMDN	A03010103 INFUSION CONTROLLERS WITH FLOW REGULATOR
MATERIALS	**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 **Luer Lock:** MABS **Caps:** HDPE / PE **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)

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PRODUCT CHARACTERISTICS

Physical/Mechanical:

Approximate total length:	2204 mm
Total internal volume of the set:	26.1 ml
Weight:	37.6 g
Input/output connectors:	Male luer lock outlet with rotating nut and female luer filter 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:	N.A. The device must be disposed after each therapy.
Filter:	No
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 8536-13	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
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

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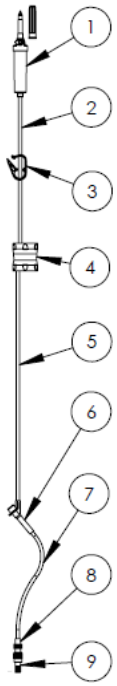
	EN ISO 15223-1 — Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements EN ISO 20417 — Medical devices — Information to be supplied by the manufacturer IEC 62366-1 — Medical devices — Part 1: Application of usability engineering 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 languages**: English / Italian / German / French / Spanish / Hungarian / Romanian
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: 3.1 Kg Devices per box: 50
CERTIFICATIONS	**ISO 9001:2015** **ISO 13485:2016** **CE Certificate (2017/745/UE)**
DRAWING	

ID	Description
1	Drip Chamber 20 drops/ml
2	Tube 65 cm – inner Ø 3.0 mm / outer Ø 4.1 mm
3	Clamp
4	Flow Regulator Easydrop® double scale
5	Tube 112 cm – inner Ø 3.0 mm / outer Ø 4.1 mm
6	Y-Injection site
7	Tube 15 cm – inner Ø 3.0 mm / outer Ø 4.1 mm
8	Male Luer Lock with rotating nut Ø 4.1 mm
9	Female luer filter

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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)
14/02/2025	01	Added Hungarian and Romanian translations on labels and IFU	Barbara Palmieri RA Specialist	Barbara Finessi QA Manage	Luca Zanini VP Healthcare and Lifesience