

Product PN	GSS037D02S	Mod. 984e-ext
Description	HI-FLO Extension Set Easydrop® double scale Y-injection site	Rev. 07

HI-FLO Extension Set with Regulator and Y-injection



PRODUCT DESCRIPTION	<p>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 outlet, compliant with ISO 80369-7.</p> <p>The set is provided with a flow regulator Easydrop® double scale, to approximately regulate the flow rate, and 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 628 mm.</p> <p>The set includes the following components:</p> <ul style="list-style-type: none"> Female luer lock with vented cap inlet; Flow regulator Easydrop® double scale, Y-Injection point; Male luer lock with cap/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 is for gravity feed infusion.</p> <p>The set is a single-use device and has to be disposed after each therapy.</p> <p>The device should only be supervised and used by qualified healthcare personnel.</p>	
CLASS OF THE PRODUCT	<p>Class Is – sterile – single use Rule 2 Annex VIII 2017/472/UE</p>	
REGISTRATION NUMBERS	<p>Italian national database: GSS037D02S 2439486</p>	
EMDN	A03020101	LOW PRESSURE EXTENSION LINES
MATERIALS	<p>Tubes: PVC (DEHP Free)</p> <p>Flow Regulator: SEBS / ABS / Alkyl Polysiloxane</p> <p>Y-injection: SEBS / MABS</p> <p>Luer Lock: MABS</p> <p>Caps: HDPE / PE</p> <p>Regulatory Compliance:</p> <ul style="list-style-type: none"> 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) 	



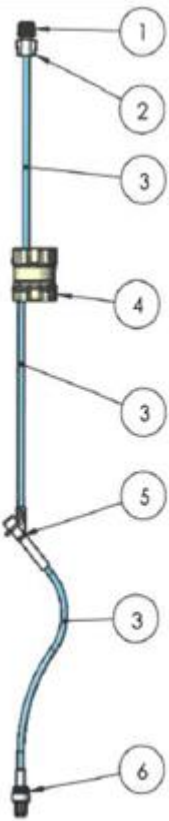
PRODUCT SPECIFICATION



Product PN	GSS037D02S	Mod. 984e-ext Rev. 07
Description	HI-FLO Extension Set Easydrop® double scale Y-injection site	

PRODUCT CHARACTERISTICS	Physical/Mechanical: Approximate total length: 628 mm Total internal volume of the set: 9 ml Weight: 17.4 g Input/output connectors: Female luer lock with vented cap inlet compliant with ISO 80369-7 Male luer lock with 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 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®/Eurodrop® single/double scale Drip Chamber: No Roller: No Y-injection site: Yes Clamp: No Tubing: PVC tube – inner Ø 3.1 mm / outer Ø 4.1 mm																																			
	5 years																																			
PRODUCT SHELF LIFE																																				
STERILIZATION	Sterile: Yes – EtO Suitable for Sterilization/Re-sterilization: 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 8536-13</td><td>Infusion equipment for medical use — Part 13: Graduated flow regulators for single use with fluid contact</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></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 8536-13	Infusion equipment for medical use — Part 13: Graduated flow regulators for single use with 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	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
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 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																																			

Product PN	GSS037D02S	Mod. 984e-ext
Description	HI-FLO Extension Set Easydrop® double scale Y-injection site	Rev. 07

	<p>IEC 62366-1 Medical devices — Part 1: Application of usability engineering to medical devices</p> <p>EN ISO 80369-1 Small-bore connectors for liquids and gases in healthcare applications — Part 1: General requirements</p> <p>EN ISO 80369-7 Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications</p> <p>EN ISO 80369-20 Small-bore connectors for liquids and gases in healthcare applications — Part 20: Common test methods</p>														
INSTRUCTIONS FOR USE	<p>Available languages: English / Italian / German / French / Spanish / Hungarian / Romanian</p>														
PACKAGING	<p>Primary Packaging: Devices are individually packed and label in medical paper bags. Bag Size: 150 X 250 mm</p> <p>Secondary Packaging: Bags are placed inside a microperforated sack.</p> <p>Tertiary Packaging: Carton Box. Box Size: 60 x 40 x 20 cm Box Weight: 3 kg Devices per box: 100</p>														
CERTIFICATIONS	<p>ISO 9001:2015</p> <p>ISO 13485:2016</p> <p>CE Certificate (2017/745/UE)</p>														
DRAWING	<div>  <table border="1"> <thead> <tr> <th>ID</th><th>Description</th></tr> </thead> <tbody> <tr> <td>1</td><td>Vented male rotating cap for female Luer Lock</td></tr> <tr> <td>2</td><td>Female Luer Lock connector Ø 4.1 mm</td></tr> <tr> <td>3</td><td>Tube 15 cm – inner Ø 3.1 mm / outer Ø 4.1 mm</td></tr> <tr> <td>4</td><td>Flow Regulator Easydrop® double scale</td></tr> <tr> <td>5</td><td>Y-Injection site</td></tr> <tr> <td>6</td><td>Male luer lock with cap</td></tr> </tbody> </table> </div>	ID	Description	1	Vented male rotating cap for female Luer Lock	2	Female Luer Lock connector Ø 4.1 mm	3	Tube 15 cm – inner Ø 3.1 mm / outer Ø 4.1 mm	4	Flow Regulator Easydrop® double scale	5	Y-Injection site	6	Male luer lock with cap
ID	Description														
1	Vented male rotating cap for female Luer Lock														
2	Female Luer Lock connector Ø 4.1 mm														
3	Tube 15 cm – inner Ø 3.1 mm / outer Ø 4.1 mm														
4	Flow Regulator Easydrop® double scale														
5	Y-Injection site														
6	Male luer lock with cap														





PRODUCT SPECIFICATION



Product PN	GSS037D02S	Mod. 984e-ext Rev. 07
Description	HI-FLO Extension Set Easydrop® double scale Y-injection site	

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	02	Added Hungarian and Romanian translations on labels and IFU	Barbara Palmieri RA Specialist 	Barbara Finessi QA Manage 	Luca Zanini VP Healthcare and Lifescience 