

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



<b>PRODUCT DESCRIPTION</b>	Extension set for infusion for intravascular applications. 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. 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. The approximate total length of the set is 628 mm. The set includes the following components: <ul style="list-style-type: none"> <li>▪ Female luer lock with vented cap inlet;</li> <li>▪ Flow regulator Easydrop® double scale,</li> <li>▪ Y-Injection point;</li> <li>▪ Male luer lock with cap/with ring and protective cap outlet.</li> </ul>
<b>MANUFACTURER NAME</b>	<b>GVS SpA</b> Via Roma, 50 40069 Zola Predosa (BO) – ITALY Phone: +39.051.6176311 – Fax: +39.051.6176200 e-mail: <a href="mailto:gvs@gvs.com">gvs@gvs.com</a> – website: <a href="http://www.gvs.com">www.gvs.com</a>
<b>INTENDED USE / APPLICATION</b>	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.
<b>CLASS OF THE PRODUCT</b>	Class I – sterile – single use Rule 2 Annex VIII 2017/472/UE
<b>REGISTRATION NUMBERS</b>	<b>Italian national database:</b> GSS037D02S 2439486
<b>EMDN</b>	A03020101 LOW PRESSURE EXTENSION LINES
<b>MATERIALS</b>	<p><b>Tubes:</b> PVC (DEHP Free)  <b>Flow Regulator:</b> SEBS / ABS / Alkyl Polysiloxane  <b>Y-injection:</b> SEBS / MABS  <b>Luer Lock:</b> MABS  <b>Caps:</b> HDPE / PE</p> <p><b>Regulatory Compliance:</b></p> <ul style="list-style-type: none"> <li>▪ Biocompatibility according to ISO 10993-1</li> <li>▪ RoHS directive 2011/65/UE</li> <li>▪ DEHP plasticizer Free</li> <li>▪ Latex free</li> <li>▪ Reach 1907/2006/CE (hazardous substances regulation)</li> <li>▪ Reg. 1272/2008/CE (classification, labelling and packaging of substances and mixtures)</li> </ul>



# PRODUCT SPECIFICATION

CE

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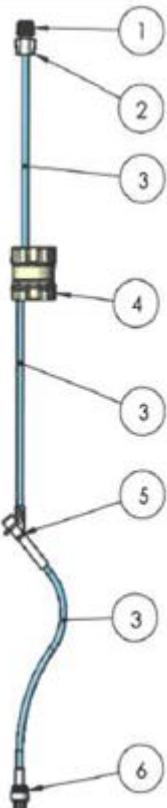
PRODUCT CHARACTERISTICS	
	<b>Physical/Mechanical:</b> Approximate total length: 628 mm Total internal volume of the set: 9 ml Weight: 17.4 g Input/output connectors: Female luer lock with vented cap inlet compliant with ISO 80369-7 Male luer lock with cap outlet compliant with ISO 80369-7 Operating temperature Range: From 5 °C to 40 °C Storage temperature Range: From 0 °C to 40 °C
	<b>Biological:</b> Biocompatibility: Compliant with ISO 10993-1
	<b>Features:</b> 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
PRODUCT SHELF LIFE	5 years
STERILIZATION	<b>Sterile:</b> Yes – EtO <b>Suitable for Sterilization/Re-sterilization:</b> No
APPLICABLE STANDARDS AND REGULATIONS	<b>Product Certification:</b> CE mark <b>Applicable Standards and Technical Regulations:</b> 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

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	IEC 62366-1 EN ISO 80369-1 EN ISO 80369-7 EN ISO 80369-20	Medical devices — Part 1: Application of usability engineering to medical devices Small-bore connectors for liquids and gases in healthcare applications — Part 1: General requirements Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications Small-bore connectors for liquids and gases in healthcare applications — Part 20: Common test methods														
<b>INSTRUCTIONS FOR USE</b>	<b>Available languages:</b>	English / Italian / German / French / Spanish / Hungarian / Romanian														
<b>PACKAGING</b>	<b>Primary Packaging:</b>  <b>Secondary Packaging:</b>  <b>Tertiary Packaging:</b>	Devices are individually packed and label in medical paper bags. Bag Size: 150 X 250 mm  Bags are placed inside a microperforated sack.  Carton Box. Box Size: 60 x 40 x 20 cm Box Weight: 3 kg Devices per box: 100														
<b>CERTIFICATIONS</b>	ISO 9001:2015 ISO 13485:2016 CE Certificate (2017/745/UE)															
<b>DRAWING</b>		<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>	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
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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	02	Added Hungarian and Romanian translations on labels and IFU	Barbara Palmieri RA Specialist 	Barbara Finessi QA Manage 	Luca Zanini VP Healthcare and Lifesience 