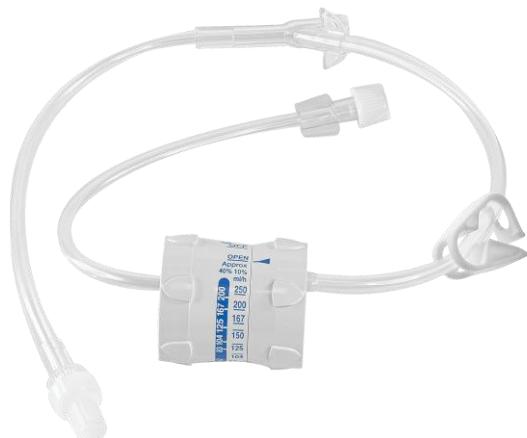


Product PN	GSS006A02S GSS007A02S GSS008A02S GSS009A02S GSS006B02S GSS007B02S GSS008B02S GSS009B02S GSS006C02S	Mod. 984e-ext Rev. 07
Description	HI-FLO Extension Set Easydrop®/Eurodrop® single/double scale Y-Infusion connector	

## HI-FLO Extension Set with Regulator and Y-injection



PRODUCT DESCRIPTION	Infusion extension set for infusion for intravascular applications. The device is sterile and is for gravity feed infusion only. The connections are a female luer lock with vented cap inlet and a male luer lock with cap ('A' and 'C' model) or male luer lock with ring and protective cap ('B' model) outlet, compliant with ISO 80369-7. The set is provided with a flow regulator Easydrop®/Eurodrop® single/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 630 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®/Eurodrop® single/double scale;</li> <li>▪ Pinch Clamp;</li> <li>▪ Y-Injection point;</li> <li>▪ Male luer lock with cap/with ring and protective cap outlet.</li> </ul>	
CONFIGURATIONS	GSS006A02S	Easydrop® single scale with male luer lock with cap outlet
	GSS007A02S	Easydrop® double scale with male luer lock with cap outlet
	GSS008A02S	Eurodrop® single scale with male luer lock with cap outlet
	GSS009A02S	Eurodrop® double scale with male luer lock with cap outlet
	GSS006B02S	Easydrop® single scale with male luer lock with ring and protective cap outlet
	GSS007B02S	Easydrop® double scale with male luer lock with ring and protective cap outlet
	GSS008B02S	Eurodrop® single scale with male luer lock with ring and protective cap outlet
	GSS009B02S	Eurodrop® double scale with male luer lock with ring and protective cap outlet
	GSS006C02S	Easydrop® single scale with male luer lock with cap outlet
MANUFACTURER NAME	GVS SpA 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>	
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 Ia – sterile – single use Rule 2 Annex VIII 2017/472/UE	
REGISTRATION NUMBERS	<b>Italian national database:</b> GSS006A02S 2439463 GSS007A02S 2439478 GSS008A02S 2439479 GSS009A02S 2439480	



# PRODUCT SPECIFICATION

CE

Product PN	GSS006A02S GSS007A02S GSS008A02S GSS009A02S GSS006B02S GSS007B02S GSS008B02S GSS009B02S GSS006C02S	Mod. 984e-ext Rev. 07
Description	HI-FLO Extension Set Easydrop®/Eurodrop® single/double scale Y-Infusion connector	

	GSS006B02S 2439481 GSS007B02S 2439482 GSS008B02S 2439483 GSS009B02S 2439484 GSS006C02S 2439485	
EMDN	A03020101	LOW PRESSURE EXTENSION LINES
MATERIALS	<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 <b>Clamp:</b> PP  <b>Regulatory Compliance:</b> <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 CHARACTERISTICS	<b>Physical/Mechanical:</b> <b>Approximate total length:</b> 630 mm <b>Total internal volume of the set:</b> 9 ml <b>Weight:</b> 17.4 g <b>Input/output connectors:</b> Female luer lock with vented cap inlet compliant with ISO 80369-7 'A' - 'C' 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 <b>Operating temperature Range:</b> From 5 °C to 40 °C <b>Storage temperature Range:</b> From 0 °C to 40 °C  <b>Biological:</b> <b>Biocompatibility:</b> Compliant with ISO 10993-1  <b>Features:</b> <b>Type of administration:</b> gravity <b>Duration of the application:</b> N.A. The device must be disposed after each therapy. <b>Filter:</b> No <b>Flow Regulator:</b> Easydrop®/Eurodrop® single/double scale <b>Drip Chamber:</b> No <b>Roller:</b> No <b>Y-injection site:</b> Yes <b>Clamp:</b> Pinch clamp <b>Tubing:</b> PVC tube – inner Ø 3.0 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	



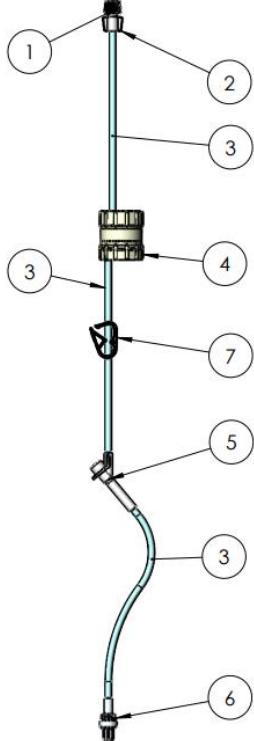
# PRODUCT SPECIFICATION

CE

<b>Product PN</b>	<b>GSS006A02S GSS007A02S GSS008A02S GSS009A02S GSS006B02S GSS007B02S GSS008B02S GSS009B02S GSS006C02S</b>	Mod. 984e-ext Rev. 07
<b>Description</b>	<b>HI-FLO Extension Set Easydrop®/Eurodrop® single/double scale Y-Infusion connector</b>	

	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
	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
<b>INSTRUCTIONS FOR USE</b>	<b>Available languages:</b>	English / Italian / German / French / Spanish / Hungarian / Romanian
<b>PACKAGING</b>	<b>Primary Packaging:</b>	Devices are individually packed and label in medical paper bags. Bag Size: 150 X 250 mm
	<b>Secondary Packaging:</b>	Bags are placed inside a microperforated sack.
	<b>Tertiary Packaging:</b>	Carton Box. Box Size: 60 x 40 x 20 cm Box Weight: 3.1 Kg Devices per box: 100
<b>CERTIFICATIONS</b>	<b>ISO 9001:2015 ISO 13485:2016 CE Certificate (2017/745/UE)</b>	

Product PN	GSS006A02S GSS007A02S GSS008A02S GSS009A02S GSS006B02S GSS007B02S GSS008B02S GSS009B02S GSS006C02S	Mod. 984e-ext Rev. 07
Description	HI-FLO Extension Set Easydrop®/Eurodrop® single/double scale Y-Infusion connector	

DRAWING			<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 3.0 mm / outer Ø 4.1 mm</td></tr> <tr> <td>4</td><td>'6' model: Flow Regulator Easydrop® single scale '7' model: Flow Regulator Easydrop® double scale '8' model: Flow Regulator Eurodrop® single scale '9' model: Flow Regulator Eurodrop® double scale</td></tr> <tr> <td>5</td><td>Y-Injection site</td></tr> <tr> <td>6</td><td>'A' – 'C' model: Male luer lock with cap Ø 4.1 mm 'B' model: Male luer lock with ring and protective cap Ø 4.1 mm</td></tr> <tr> <td>7</td><td>Pinch Clamp</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 3.0 mm / outer Ø 4.1 mm	4	'6' model: Flow Regulator Easydrop® single scale '7' model: Flow Regulator Easydrop® double scale '8' model: Flow Regulator Eurodrop® single scale '9' model: Flow Regulator Eurodrop® double scale	5	Y-Injection site	6	'A' – 'C' model: Male luer lock with cap Ø 4.1 mm 'B' model: Male luer lock with ring and protective cap Ø 4.1 mm	7	Pinch Clamp
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 3.0 mm / outer Ø 4.1 mm																		
4	'6' model: Flow Regulator Easydrop® single scale '7' model: Flow Regulator Easydrop® double scale '8' model: Flow Regulator Eurodrop® single scale '9' model: Flow Regulator Eurodrop® double scale																		
5	Y-Injection site																		
6	'A' – 'C' model: Male luer lock with cap Ø 4.1 mm 'B' model: Male luer lock with ring and protective cap Ø 4.1 mm																		
7	Pinch 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 Lifescience 