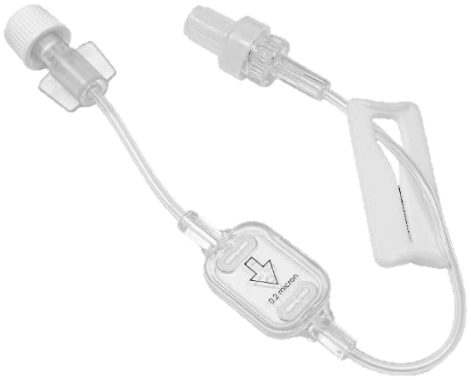
PRODUCT SPECIFICATION

CE 0051

Product PN	**GSS051A01S GSS052A01S GSS053A01S GSS054A01S**	**Mod. 984e-ext**
Description	**HI-FLO Extension Set Neonatal 0.2/0.2+/1.2/5.0 µm**	**Rev. 07**

HI-FLO Extension Set Neonatal with 0.2/0.2+/1.2/5.0 µm Filter



PRODUCT DESCRIPTION	Infusion 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 vented Speedflow® Neonatal filter, with an hydrophilic PES membrane with 0.2/0.2+/1.2/5.0 µm pore size for particles retention and a hydrophobic PTFE membrane with 0,03 µm pore size. The set is provided with a plate clamp. The approximate total length of the set is 209 mm. The set includes the following components: ▪ Female luer lock with vented cap inlet; ▪ Speedflow Neonatal 0.2/0.2+/1.2/5.0 µm IV Filter; ▪ Clamp piatta; ▪ Rotating male luer lock with cap outlet.
CONFIGURATIONS	**GSS051A01S** 0.2 µm filter **GSS052A01S** 0.2+ µm filter **GSS053A01S** 1.2 µm filter **GSS054A01S** 5.0 µm filter
MANUFACTURER NAME	**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
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 can be used either for gravity or in combination with an infusion set or an infusion device (pump or syringe). The set is intended to retain different particles depending on its filter pore size: ▪ 0.2 µm filter is intended specifically to eliminate air bubbles and to retain particles and bacteria, ▪ 0.2+ µm filter is intended specifically to eliminate air bubbles and to retain particles, bacteria and endotoxins, ▪ 1.2 µm filter is intended specifically to eliminate air bubbles and to retain fungi and microorganisms, ▪ 5.0 µm filter is intended specifically to eliminate air bubbles and to retain particles. 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; ▪ Devices with 0.2+ µm filter: up to 120 hours. The set has to be disposed after each therapy. Sets with 0.2/0.2+ 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. Sets with 5.0 µm filter cannot be used for infusion therapy without further bacterial retention filter. 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

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Description	HI-FLO Extension Set Neonatal 0.2/0.2+/1.2/5.0 µm	Rev. 07

REGISTRATION NUMBERS	**Italian national database:** **GSS051A01S** 2439415 **GSS052A01S** 2439420 **GSS053A01S** 2439421 **GSS054A01S** 2439423
EMDN	**A03020101** LOW PRESSURE EXTENSION LINES
MATERIALS	**Filter media:** PES Hydrophilic membrane / PTFE Hydrophobic membrane / 0.2+ filters include also Polyethylenimine **Filter housing:** MBS **Tubes:** PVC **Luer Lock:** ABS / PVC **Caps:** HDPE / PE **Clamp:** PP **Regulatory Compliance:** ▪ 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 CHARACTERISTICS	**Physical/Mechanical:** **Approximate total length:** 209 mm **Total internal volume of the set:** 0.5 ml **Weight:** 7.7 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 **Maximum applicable pressure:** 3,2 bar **Biological:** **Biocompatibility:** Compliant with ISO 10993-1 **Features:** **Type of administration:** gravity / pressure **Duration of the application:** 0.2 µm up to 96 hours 1.2 µm up to 24 hours 0.2+ µm uo to 120 hours **Filter:** Speedflow Pediatric 0.2/1.2/0.2+/5.0 µm vented **Filter pore size:** 0.2/1.2/0.2+/5.0 µm **Filter internal volume:** < 0.35 ml **Filter media:** hydrophilic PES membrane and hydrophobic PTFE membrane, 0.2+ filters include also Polyethylenimine **Flow Regulator:** No **Drip Chamber:** No **Roller:** No **Y-injection site:** No **Clamp:** Plate clamp **Tubing:** PVC tube – inner Ø 1.0 mm / outer Ø 2.0 mm
PRODUCT SHELF LIFE	5 years
STERILIZATION	**Sterile:** Yes – EtO **Suitable for Sterilization/Re-sterilization:** No

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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 8536-9	Infusion equipment for medical use — Part 9: Fluid lines for single use with pressure infusion equipment
EN ISO 8536-11	Infusion equipment for medical use — Part 11: Infusion filters for single use with pressure infusion equipment
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
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: 130 X 200 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 kg
Devices per box: 300

CERTIFICATIONS

ISO 9001:2015
ISO 13485:2016
CE Certificate (2017/745/UE)

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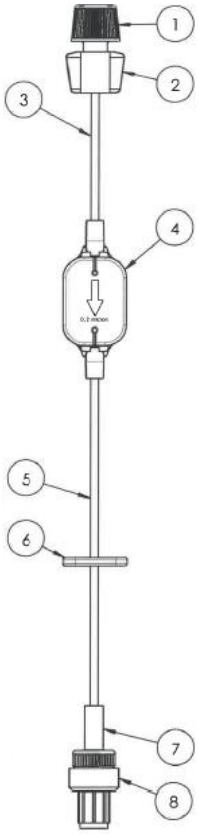
DRAWING



ID	Description
1	Vented male rotating cap for Female Luer Lock
2	Female luer lock connector Ø 2
3	Tube 5 cm – inner Ø 1.0 mm / outer Ø 2.0 mm
4	'51' model: Speedflow Neonatal 0.2 µm IV filter '52' model: Speedflow Neonatal 0.2+ µm IV filter '53' model: Speedflow Neonatal 1.2 µm IV filter '54' model: Speedflow Neonatal 5.0 µm IV filter
5	Tube 10 cm – inner Ø 1.0 mm / outer Ø 2.0 mm
6	Plate clamp
7	Male luer lock connector Ø 2 mm
8	Cap for male luer lock

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