PRODUCT SPECIFICATION

Product PN	RN067 – RN130 – RN200 – RN201 –	☐ PRELIMINARY	Mod. 984c
Description	EASYDROP-EURODROP; IV Flow regulators	☐ R&D RELEASED	Rev. 05
		☑ RELEASED	

EASYDROP-EURODROP – IV Flow Regulators

Easydrop

Eurodrop

PRODUCT DESCRIPTION	**EASYDROP-EURODROP – IV Flow Regulators** **It is a non-sterile product provided in bulk packs for further manufacturing**
INTENDED USE / APPLICATION	**The graduated flow regulators single use, for IV Set, to control the flow of intravenous infusion solutions with fluid contact under gravity feed conditions.**
MATERIALS	**Housing Polymer**: White ABS **Gasket**: Clear SEBS **Lubricant:** Silicone pure - medical grade **Ink:** used only for scale printing **Inlet/Outlet connectors:** Standard IV tubing connectors **Regulatory Documentation Required:** ☑ Biocompatibility according ISO 10993-1 ☑ Rohs compliance ☑ BSE/TSE in compliance ☑ DEHP plasticizer Free and latex free ☑ Reach 1907/2006/CE (hazardous substances regulation) ☑ Conflict minerals

PRODUCT CHARACTERISTICS	**Physical/Mechanical:** **Dimensions:** **Weight: 9 g** **Operating temperature Range:** up to 40°C **Maximum Operating pressure:** 0.5 bar in static condition, gravity set **Storage temperature Range:** From 0 °C to 45 °C **Chemical:** **Compatibility to solvents**: Cycloexanone **Biological:** **Pyrogenicity:** < 0.25 EU/ml using the LAL test method **Tolerances of flow rate**: Range 5-15 ml/h not defined. Range 20 ml/h tolerance on flow rate -10/ +50% Range 21-83 ml/h tolerance on flow rate -10/ +30% Range 84-350 ml/ h tolerance on flow rate -10 / +20% **Stability of flow rate**: 10% flow rate fluctuation during 24 hours infusion (tested with NaCl 0,9% solution from glass bottles) **Air test tightness:** 0,5 bar 15 s. Static condition- position on the scale:OPEN

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INSTRUCTIONS **WARNINGS**	Place the I.V. solution container at about 80 cm above the outlet level. Connect the I.V. set to the container. Connect the extension set with Easydrop to the I.V. set (not necessary if Easydrop is already contained in I.V. set) Open the clamp to begin priming the line Check that liquid is coming out from the end of the line. Easydrop is provided by GVS in the OPEN position. PRIME Easydrop completely turning Easydrop from OPEN position to OFF position and then adjust the Easydrop scale to the required value. Connect the I.V. line to the catheter or needle. Double check that Easydrop is delivering the required flow rate by counting the drops In order to change the flow rate adjust height of I.V. solution container. Raise the container to increase the flow rate, lower the container to decrease it. **Note:** *Easydrop scales have been calibrated according to GVS standard test conditions. Head pressure 80 cm (Head pressure is considered the differential height between the inlet and outlet of liquid in the I.V set). Standard ISO8536-13 gravity I.V. line: vented drip chamber 20 drops/ml with 15 micron filter, tubing 3.0x 4.1 mm, Y-site connector downstream with the Easydrop and Male Luer lock connector at the end of the line. Needle used is 20G, 36 mm length. Total length of the line 150 cm. Liquid used: NaCl 0.9% physiological solution. Changing of any of the above parameters can cause a different response in flow regulation. **IMPORTANT** Do not use Easydrop in OPEN position, this will cause an uncontrolled liquid delivery (about 3 liters/hour). Easydrop cannot be used for the administration of blood or blood originated products. Using a high viscosity solution can cause a lower flow rate than indicated on the scale. Compensate for this by increasing the head pressure applied. Use of a 15 micron filter on the drip chamber is suggested in order to prevent crystals from blocking the fluid path inside Easydrop. Drop counting is always necessary in order to confirm proper flow rate. If necessary, adjust the height of the I.V. solution container to increase or decrease the flow rate. Example: 200 ml/h with a 20 drops/ml drip chamber means 66 drops per minute. 100 ml/h with a drip chamber 20 drops/ml means 33 drops per minute. **Remove the external bag before planting into a clean room.** **Cyclohexanone for glueing is recommended. Nevertheless, if cyclohexanone drops enter into the flow regulator body can close channel clogging.** **Verify compatibility of drugs to use with the raw materials declared in specifications.** **It is not recommended to use any kind of disinfectant in direct contact with the flow regulator.** **For more details, please contact GVS.**
PRODUCT SHELF LIFE	**5 years of life-time**, at indoor storage condition, not exposed to sunlight, from the date reported on the barcode label. While GVS S.p.A. is able to provide general guidelines, it is important to note that it is responsibility of the device manufacturer to validate each product – its life-time and performances after the assembly and sterilization process- for its intended medical application.
STERILIZATION	**SUITABLE FOR STERILIZATION : :** ☑ Yes ☐ No ☑ EtO; max 44 °C ☑ Gamma; max 25 kGy Higher temperature can cause a reduction in performance. Please contact GVS.
APPLICABLE STANDARDS AND REGULATIONS	In compliance with ISO 8536-13:2016 Infusion equipment for medical use — Part 13: Graduated flow regulators for single use with fluid contact

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PACKAGING AND LABELLING

The product is provided in bulk packs for further manufacturing, processing or repackaging.

PACKAGING
1.500 pieces (box) are packed in a double PE bag. Bags are separately hot sealed.

LABELLING
The first bar code label is outside 2 bags.
The second bar code label is stuck outside the box.
Each bag is labelled with the following traceability information:

- Quantity
- Product description
- Product date
- Lot number (OL and batch number to trace back to raw materials used)
- Operator code

Different lot of goods in one shipment are packed in a manner to prevent mixing.
Different lot in one box are separately closed and separately labelled to prevent mixing.

CERTIFICATE OF COMPLIANCE

Conformity declaration is printed by System, on each document of transport together with the complete traceability number of the goods.
The Quality management system is in compliance with ISO 9001, ISO 13485.

DRAWING

The attached drawing is part of this material specification and must not be duplicated or made accessible to a third party without prior consent.

ACCEPTABLE QUALITY LEVEL

AQL with sampling Plan: ISO 2859 part.1

VISUAL REQUIREMENTS

Visual acceptance requirements apply when inspected under below conditions:

Magnification: unaided eye, approximately 45 cm (18'') from eye
Light type: Fluorescent
Timings: 5 s per unit

Sampling plan according to ISO 2859 part 1 – 1st Level inspection, single sampling plan, normal inspection.
Embedded particulate Matter: according to Dirt Estimation Chart

	Acceptance Requirement	AQL	Sampling Plan
1	Insufficient graphic quality	0,65	ISO 2859 part. 1 1st General inspection Levels
2	Embedded particles > 0.2 mm^2 (visual for 5'' at a distance pf 300-450 mm)	0,65	
3	Wrong position of indicator respect to ON and OFF position > 0,8 mm	0,65	
4	Wrong assembly	0,65	
5	Dents leaving traces	0,65	
6	Burns	0,65	
7	Damaged connectors	0,65	
8	Print smudged > 2 of 1 mm^2 or > 4 of 0,25 mm^2	0,65	
9	Partially absence of printing	0,65	
10	Damaging or deformation	0,65	
11	Loose particulate matter	0,65	

Contamination Loose PM: free of visible particles >0,2 mm^2

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PERFORMANCE REQUIREMENTS

Acceptance Requirement			AQL	Sampling Plan
1	Functional test Flow rate test	Tolerances of flow rate: Range 5-15 ml/h not defined. Range 20 ml/h tolerance on flow rate -10/ +50% Range 21-83 ml/h tolerance on flow rate -10/ +30% Range 84-350 ml/ h tolerance on flow rate -10 / +20%	0,4	ISO 2859 part. 1 S3 Special inspection level
2	Functional test Water Tightness test	Pressure 0.5 bar for time 4 seconds Fill the flow regulator with water and apply pressure. During test, make 4 complete rotation from OPEN to Off. No leakage admitted	0,4	
3	Functional test Leakage water tightness test	Pressure 80 cmH_2O gravity for time 5 minute Position on the scale: OFF Static condition	0,4	
4	Functional test AIR test tightness	Pressure 0.5 bar for time 15 sec. Static condition Position on the scale: OPEN	0,4	

This material specification describes the properties of product above indicated.
This document contains general requirements, material description, drawing references, defect specification, biological material requirements.

REVISIONS AND APPROVALS:

DATE	REV.	*REASON FOR CHANGE*	ISSUED AND CONTROLLED BY: (name /function and signature)	APPROVED BY: (name /function and signature)
09/03/2020	08	This revision replaces the previous rev.7, in this rev.8, it was added the compliance with ISO 8536-13:2016. Performance table; described better the functional tests.	Chiara Porcu Project Manager	Isabella Frignani Assurance Quality Process Product

Customer Approval:

We accept this material specification as a part of the agreed terms of delivery

Company name _____

Approved by: _____
(Name, Function) (Signature)

Date _____ _____
(Company stamp)

Please send back this document signed for approval. If we will not receive this specification signed , we consider the first order placed as implicit approval.