PRODUCT SPECIFICATION

Product PN	**RN401ANAK0000A00**
Description	Pump connector 8x12 tube, heparin 2 O.D. - DEHP FREE

Mod. 984

Rev. 02

PUMP CONNECTOR 8x12 tube heparin 2 O.D. - DEHP FREE

PRODUCT DESCRIPTION	Pump connector for 8x12 tube heparin 2 O.D. – DEHP FREE Is a non-sterile pump connector The product is provided in bulk packs for further manufacturing.
MANUFACTURER NAME	GVS Sud S.r.l. Via Tavernole, 8 83030 Manocalzati (AV) – ITALY
INTENDED USE / APPLICATION	Hemodialysis
MATERIALS	**Housing:** Soft PVC DEHP FREE – natural color **Softener**: TEHTM (Tri-2-ethylhexyl trimellitate; TOTM) **For raw materials used to produce component, Regulatory Documentation Required:** ☒ Test performed in compliance with USP class VI and/or ISO 10993-1. ☒ Reach 1907/2006/CE (hazardous substances regulation) ☒ Rohs, directive 2002/95/CE ☒ BSE/TSE, directive 2003/32/CE ☒ DEHP plasticizer Free ☒ Latex free ☒ Conflict minerals
PRODUCT CHARACTERISTIC	**Weight** : 2,37gr **Dimensions:** Length - 30 mm; Height 18 mm
PRODUCT SHELF LIFE	5 years After 2 years, from the date of production, the color has a change of tonality from clear to brownish; this is due to natural change of the raw material, that has not an impact with the functionality characteristics of the product.
STERILIZATION	Ethylene oxide
PACKAGING AND LABELLING	5.000 pcs packed in two PE bags. Bags are separately closed. The first bar-code label is between the 2 bags. The second bar-code label is stuck outside the box.

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Each bag is labeled 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 mix-ups.
Different lots in one box are separately closed and separately labeled to prevent mix-ups.

CERTIFICATE OF COMPLIANCE

Conformity declaration is printed on every invoice and Certificate is according to
UNI EN 10204 type 2.1
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 written GVS S.p.A. consent.

VISUAL REQUIREMENTS

Visual acceptance requirements apply when inspected under below conditions:

Instrument inspection with naked eye and light source
Distance of 300-450 mm.
Timings: 5 sec per unit

	Acceptance Requirement	AQL	
1	Incomplete plastic support	0,25	Sampling plan according to ISO 2859 part. 1 – 1st Level inspection, single sampling plan, normal inspection.
2	Serious shrinkages of material compromising the functionality of the part	0,25	
3	Broken part	0,25	
4	Marks or scratches with residual	0,25	
5	Burnings	1	
6	Flashes > 0,3 mm	1	
7	Jutting injection gate > 0,3 mm	1	
8	Incompleteness's not compromising the functionality of the part	1	
9	Mould, rust dirty	1	
10	Loose particulate matter > 0,2 mm^2	1	
11	* Embedded particulate matter > 0,2 mm^2 (if ≤0,2 mm^2 max 3 per viewing area)	1,5	
12	air bubbles > 0,4 mm^2	1,5	

*Embedded Particulate Matter and air bubbles : according to Dirt Estimation Chart (Tappi Standard).

FILTER TECHNOLOGY

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PERFORMANCE REQUIREMENTS

	Acceptance Requirement		AQL	Sampling Plan
1	**Dimensional**	Ø for main connection	0,1	Sampling plan according to ISO 2859 part. 1 – S3 Special inspection level, single sampling plan, normal inspection
2	**Dimensional**	Ø for tube pump connection	0,1	
3	**Dimensional**	Ø for heparin connection	0,1	

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)
16/05/2016	01	This revision replaces the previous rev.00. In this rev. 01 it was changed the layout of the module and it was added the shelf life.	Isabella Frignani Process Quality Assurance Isabelle Frignani	Tiziana Landi Quality Assurance

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.