

PRODUCT SPECIFICATION

Product PN	TA225CV290000E01 - green	<input checked="" type="checkbox"/> PRELIMINARY	Mod. 984c Rev. 05
Description	OPEN TIP PROTECTOR FOR LUER LOCK in PP green without membrane	<input checked="" type="checkbox"/> R&D RELEASED <input checked="" type="checkbox"/> RELEASED	

OPEN TIP PROTECTOR FOR LUER LOCK in PP green



PRODUCT DESCRIPTION	Open tip protector for luer lock non-sterile. The product is provided in bulk packs for further manufacturing.		
INTENDED USE / APPLICATION	Describe application For easy priming procedure in with elastomeric standard pump.		
MATERIALS	Item	Material	Color
	Frame/Housing	Polypropylene (PP) + Masterbatch	Green
Regulatory Documentation Required: <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Biocompatibility according ISO 10993-1 <input checked="" type="checkbox"/> Rohs, directive 2002/95/CE <input checked="" type="checkbox"/> BSE/TSE, directive 2003/32/CE <input checked="" type="checkbox"/> DEHP plasticizer Free and latex free <input checked="" type="checkbox"/> Reach 1907/2006/CE (hazardous substances regulation) <input checked="" type="checkbox"/> Latex free <input checked="" type="checkbox"/> BPA and pthathalates free <input checked="" type="checkbox"/> Conflict minerals 			

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PRODUCT CHARACTERISTICS		Dimensions: Outside diameter 7,83 mm Total height 18,60 mm Female connector in compliance with ISO 80369-7			
PRODUCT SHELF LIFE		5 years			
STERILIZATION		STERILE : <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No SUITABLE FOR STERILIZATION : : <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> EtO; <input checked="" type="checkbox"/> Gamma;			
PACKAGING AND LABELLING		50.000 pcs packed in two PE bags separately closed. The first bar-code label is placed between the 2 bags. The second bar-code label is attached outside the carton. Each bag is labeled with the following traceability information: <ul style="list-style-type: none">- Quantity- Product description- Product date- Lot number (OL and 6 digit 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 carton are separately closed and separately labeled to prevent mix-ups.			
CERTIFICATE OF COMPLIANCE		With each shipment, GVS SpA Customer Service will send the CoC to the Customer, based on the lot numbers and date of manufacture. 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 consent.			
ACCEPTABLE QUALITY LEVEL		<input checked="" type="checkbox"/> AQL see below table			

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VISUAL REQUIREMENTS	Visual acceptance requirements apply when inspected under below conditions: Magnification: None Light type: naked eye + lamp Timing: 5 sec per unit Distance: 30-45 cm				
	Acceptance Requirement		AQL	Sampling Plan	
	1	Plastic support incomplete	0,1	Sampling plan according to ISO 2859 part. 1 – 1 st Level inspection, single sampling plan, normal inspection.	
	2	Deformations/squeezed parts	0,1		
	3	Porosities, shrinkages	0,1		
	4	Burns	0,1		
	5	Shrinkage on injection site	0,1		
	6	Bubbles	0,1		
	7	Dirty, grease on the part	0,1		
	8	Rust on the part	0,1		
	9	Flashes > 0,2 mm	1		
	10	Threads	1		
	11	*Embedded particulate matter > 0,3 mm ²	1,5		
	12	Not uniform coloring/streaks	1,5		
13	Scrapes	1,5			
14	Embedded or loosing dirt not compromising the functionality of the part	1,5			
15	*Loose contamination >0,1mm ²	1,5			
* Embedded Particulate Matter and Loose particulate matter: according to Dirt Estimation Chart					
DIMENSIONAL REQUIREMENTS	Acceptance Requirement		Value of reference	AQL	Sampling Plan
	1	Internal diameter of female luer lock	4.248 +/- 0.05 mm 3.843 +/- 0.05 mm ISO 80369-7	0,1	ISO 2859 part. 1 – S3 Special inspection level

This material specification describes the properties of product above indicated.

This document contains general requirements, material description, drawing references, defect specification, biological material requirements.

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REVISIONS AND APPROVALS:

DATE	REV.	REASON FOR CHANGE	ISSUED AND CONTROLLED BY: (name /function and signature)	APPROVED BY: (name /function and signature)
19/01/2021	00	First emission	Elsa Caruso – RP <i>Elsa Caruso</i> Paolo Saragoni – Engineering Manager	Luca Zanini – Sales VP <i>Luca Zanini</i> Tiziana Landi – DAQ <i>Tiziana Landi</i>

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.