



Mark VII Max

November 2017

# 1. Technical criteria

1.2. Style, Design, Construction & Function

1.1. R	1.1. Regulatory Compliance / Site Quality Management System							
Nº	Criteria	Description	Options	Remarks				
1	ISO	Certified according to DIN EN ISO 9001:2008	Copy upon request					
2	ISO	Certified according to DIN EN ISO 22716: 2007	Copy upon request					
3	FDA	Drug Master File (DMF 22653, Type III) for primary packaging material	LOA upon request	For products sold in US				

N°	Criteria	Description	Options
1	Style, design and construction	The Pump will conform in style, design and construction to the technical drawing as indicated in section 4	
2	Basic nominal output is available at: 0,16ml/stroke, 0,21ml/stroke, 0,30ml/stroke. Output average varies ±20% of the target volume. The Snap on closure options GS30 and GS31 output is		Nominal output is adjustable upon request
3	Priming	The number of strokes for priming of the pump is not specified. It depends on the relevant dip tube length and the physical properties of the used medium	

_		The Snap on closure options GS30 and GS31 output is	upon request
		$0.180$ ml/stroke with a tolerance of $\pm 20\%$ of the target volume.	upon request
		internal Test liquid: 99% Ethanol	
	Drimina	The number of strokes for priming of the pump is not specified.	
3	Priming	It depends on the relevant dip tube length and the physical	
		properties of the used medium	
4	Spray Pattern	The spray pattern shall be a nearly circular pattern. There should	
4		be no indication of a steady stream.	
		As long as the recommended application torque is applied and	
5	Seal	the bottle standards are fullfilled the sprayer-gasket seals	
		towards the bottle. (Section 4.5)	
6	Hood retention	The hood retention force will withstand an instantaneous direct	
	force	vertical pull, no less than 4 N.	
7	Actuation force	The actuation force results of the spring load and the stream	
	7 retuation force	resistance of the liquid. It is not specified	
		The diptube retention force will withstand an instantaneous	
	Dip Tube retention force	direct vertical pull of not less than 10 N. This guarantees that the	
8		diptube will not drop off the accumulator during a controlled	
		assembly (e.g. screwing) process onto a bottle or a tear off of the	
$\vdash$		tube	
9	Closure:	The closure will turn without excessive interference and/or drag	
	End of the Dip	Standard: with V-cut. This allows unaffected priming in case	
10	Tube	of contact of the Dip Tube with the wall or the bottom of the	
	Tuoc	bottle	
		Length complies with the relevant bottle length with a precision	
		of $\pm 2$ mm under gasket.	
		Technical wise:	
11	Dip Tube	DTL from 60mm up to 250mm possible (but with upcharge for	*TBD
**	Length (DTL)	DTL shorter than 65mm and longer than 200mm)	122
		Performance wise: the use of a dip tube longer than 100mm	
		should be checked by our laboratory because the performance is	
		effected by the used formulation	



#### Mark VII Max

November 2017

12	Dip Tube	Slightly curved on freshly assembled items	
12	Dip Tube	(see 1.4 recommendation for proper use)	
		Workmanship must be first class throughout the process to	
13	Aesthetics	ensure that the pump is free of any defect that will affect its	
		quality image	
14	Licago	The pump specification with Spray Extender can be assembled	
14	Usage	with a clip to avoid unintended usage	
15	Color	The color is verified against the approved color chip	

All above listed performance values of the individual criteria are based on tests one week after assembly and at a temperature up to 25°C max.

All criteria are verified according to applicable test methods from SILGAN

#### 1.3. Classification of Non-Conformances

Class	AQL	Type	Description
Critical	0,04	Safety	Hazardous or unsafe condition for individuals handling or using product
		Performance	Fails to meet design performance specifications
		Regulatory	Violation of governmental requirements
		Material	Components produced from non specified material
			Subassembly or final assembly produced with non specified components
		Hygiene	Essential contamination
Major	0.65	Dimensional	Fails to meet specified dimensional tolerances
		Performance	Fails to meet design performance specification
		Joint security	Fails to meet joint security specifications
		Leakage	Fails specified leak test requirements
		Aesthetic	Any appearance non-conformance that may cause the consumer to select another package
Minor	2.5	Aesthetic	A defect will be classified as minor if it is not likely to reduce the product's stability, but reflects poor workmanship.

The product inspection is made at different steps according to the control plans both on quantities and frequencies established by the manufacturing site:

The customer's non-conformities are managed by SILGAN Customer Service and Quality Assurance. In order to aid in the investigation of root cause, defective samples preferably not manipulated are needed as well as a label identification of the affected lots. In addition information indicating the total quantity of affected material and the estimated percentage of defective units.

<sup>\*</sup> TBA = to be agreed (within technical limitations)

<sup>\*</sup> TBD = to be determined (within technical limitations)



10

# **Technical Product Specification**

Mark VII Max

November 2017

1.4. R	Recommendations for Qualification a Proper Use
Nº	Criteria
1	Storage temperature should remain between 5°C and 25°C. Boxes should be kept in dry place. Short time storage (maximum 4 weeks) at a temperature range between 0°C and 40°C is possible
2	Storage life recommendation is no more than 1 year in suitable store conditions, between SILGAN production and customers filling process
3	The package is leak-proofed under normal conditions and shall not be squeezed extremely
4	Pump shall be used only in upright position
5	Cartons and bags to be handled with care. Cartons shall not be turned and stored up side down
6	This Pump is sold as a non-sterile product. It is produced non-sterile.
7	Compatibility test is recommended before first use of pump specification and after formulation changes
8	Normally the use is self-explanatory, but may require some additional instructions for the consumer.
9	Bottle neck to be checked carefully for proper fitment and save sealing; Drawings and bottles to be checked by SILGAN upfront. Bottle types and supplier recommendation on request The bottle neck shall comply to the applicable recommendations of the material and size of the neck used.

We recommend to apply the application torque as mentioned in section 4.



## Mark VII Max

November 2017

No.	Component	Material Type
2	Orifice	POM
3	Piston	PE-HD
4	Poppet	PP (clear)
5	Small Piston	PE-HD
6	Accumulator	PP
7	Ball	Stainless Steel
		High Alloy Stainless Steel
8	Spring	Stainless Steel
		High Alloy Stainless Steel
9	Closure	PP
10	Insert	PP
11	Hood	PP (clear)
		SB
		SB
12	Dip Tube	PE-LD / PP
13 Gasket		EVA
		PE-EVA/foamed EPE
		PE-LD / PIB Compound
14	Ferrule	Al Mg
16	Spray Head	PP
	Spray Extender	PP
16	Spray Extender	PP
17	Snap Body	PP
19	Snap-On Closure	POM
25	Stopper	PP
34	Regulator	PE-LD
Additi	ves	
	Lubricant	Polydimethyl - Siloxane
	Slip Agent	PE
	Antistatic Agent	PP
Colors		
	Color, white	PP
	Color, white	PE



Mark VII Max

November 2017

#### 2.2. Regulatory Compliance Policy

SILGAN Dispensing Systems has testing and / or supplier's assurances that the polymers and polymeric components used in the production of the packaging product listed above :

- do not intentionally contain lead, cadmium, mercury and hexavalent chromium and are in compliance with the requirements of CONEG legislation and of EU Directive 94/62/EC.
- meet the requirements of EC regulation no. 10/2011 relating to plastic materials and articles intended to come into contact with foodstuffs (as amended)
- meet the relevant applicable FDA regulations on food contact (21 CFR) or are Generally Recognized as Safe
- Suppliers have confirmed that they do not use or add Phthalates. Phthalates may be contained only in trace amounts due to the catalyst systems used for manufacturing of the polymers, mainly Polypropylene.
- Suppliers have confirmed that they do not use components from animal sources to manufacture the polymers. If components of animal origin are used as production aids all necessary measures have been taken to exclude the risk of transmission of TSE or BSE, e.g. EMEA/410/01 or comparable.

To be verified for the final pump specification.

Ultimately customers must make their own determination that their use of our products is safe, lawful and technically suitable in their intended applications.

The packaging is not produced with the intention of multiple use (reuse).

SILGAN customers must consider the particular purpose for which they intend to use our products in verifying the suitability of our products for those intended applications. SILGAN makes no implied or express warranty of fitness for any particular purpose.

The packaging component is not bio-degradable; it can be used as a source of energy after separation into component parts; the packaging can be used for recycling.

We maintain adequate documentation in support of this certification, including that of any exceptions permitted by the legislation. We will make documentation available for inspection and supply copies without charge to government agencies.

## 3. Compatibility Product Policy

In response to customer request, SILGAN will conduct certain product compatibility tests.

These test results will be shared with customers for preliminary and comparative product evaluation purposes only.

Sharing of test results is intended to communicate neither express nor implied warranties of fitness for any particular purpose or customer end use. SILGAN customers must independently evaluate the suitability of our products for their planned applications and should not refer to SILGAN preliminary test results as evidence of technical suitability.

Customer must always make the final decision.



#### Mark VII Max

November 2017

Description	
Range of various Actuators :	*TBA
Compact Head, Head with fingergroove, Rhapsody Head and Spray Extender	

### 4.3 Dip Tube

Description	L
Mark VII Max (all versions) – the length of interest is always determined from "under Gasket"	*TBA

#### 4.4 Fitments

Description	Ø (mm)	E (mm)	F (mm)	H (mm) without Gasket	Pitch (mm)
<u>Screw Closures</u>					
GL 20	23,4	15,5	25,7	14,3	3
GPI 20-400	23,6	12,5	22,7	11,3	3,175
GPI 20-410	24,3	15,9	26,1	14,1	3,175
GPI 22-415	27,3	23,2	33,4	21,3	3,175
GPI 24-410	28,9	18,4	28,6	16,4	3,175
Ferrule					
B 20 x 7 (standard)	21,1	7		5,5	
B 20 x 8 (standard)	21,1	8	/	6,5	
B 20 x 7 (updraw dome)	21,1	7		5,5	
B 20 x 7,45 (updraw	21,1	7,45		5,95	
dome)					
<u>Snap-On Closures</u>					
GS 30	32,3	6		5	
GS 31	33,6	6		5	

Gasket thickness depends on used bottle and material Screw Closure and Ferrule = 1,00mm or 1,25mm Snap on Closure GS 30 and GS 31 = 1,2mm

#### 4.5 Bottle necks

Designation of thread acc. GPI standard	Outer diameter of thread (mm)	Inner diameter of thread (mm)	Height of thread (mm)	Recommended application torque (Nm)	Number of turns
<u>Screw Closures</u>					
GL 20	20	18	10,5	0,113	~ 2
GPI 20-400	19,7	17,5	11,8	0,113	~ 1,5
GPI 20-410	19,7	17,5	8,7	0,113	~ 1,5
GPI 22-415	21,7	19,5	13,5	0,130	~ 2,5
GPI 24-410	23,6	21,5	10,7	0,158	~ 2
Designation of neck	Outer diameter	Snap-Bead height			
acc. to FEA standard	of neck	(mm)			
	(mm)				
<u>Ferrule</u>					
B 20 x 7 (standard)	20	~3,2	acc. to FEA standard		
B 20 x 8 (standard)	20	~3,8	acc. to FEA standard		
B 20 x 7 (updraw dome)	20	~3,2	acc. to FEA standard		
B 20 x 7,45 (updraw dome)	20	~3,5	acc. to FEA standard		
Snap-On Closures					
GS 30	~30,4	~2,7		special neck design	
GS 31	~31,7	~2,9		special neck design	

- FEA Fédération Européenne des Aérosol; Brussels (www.aerosol.org)
- Min ID of bottle neck > 11,8mm
- Bottle neck recommendation drawings on request

Bottle neck to be checked carefully for proper fitment and secure sealing.

Drawings and bottles to be checked by SILGAN upfront.

Recommended bottle types and supplier recommendation on request.