

**ITEM** : 3 PARTS 50 ML PERFUSION SYRINGE WITHOUT NEEDLE

**DESCRIPTION** : Sterile hypodermic 3 Parts 50ml syringe without needle for single use that is made of plastic material, apyrogenic, non-toxic, and sterilized with ethylene oxide. They are used in perfusor devices to deliver a certain amount drug to the patient at a certain time.

**Reference Number : 81590**

**PHYSICAL PROPERTIES**

<u>PHYSICAL PROPERTIES</u>	<u>STANDARD (TEST METHOD)</u>	<u>UNIT</u>	<u>RESULT</u>																		
Material	TS EN ISO 7886-2 TS EN ISO 7886-1 TS EN ISO 7864	- - -	Medical polypropylene, polyethylene and synthetic rubber Medical polypropylene and stainless steel																		
Capacity	TS EN ISO 7886-2 TS EN ISO 7886-1	ml	50 (± % 4)																		
Dead Space	TS EN ISO 7886-2 TS EN ISO 7886-1	ml	Not greater than 0,20																		
Total Graduated Capacity	TS EN ISO 7886-2 TS EN ISO 7886-1	ml	50																		
Dimensions	TS EN ISO 7886-2 TS EN ISO 7886-1	mm	<table border="1"> <thead> <tr> <th></th> <th>Type 1</th> <th>Type 2</th> </tr> </thead> <tbody> <tr> <td>Ø inside</td> <td>= 28,70</td> <td>28,70</td> </tr> <tr> <td>Ø outside</td> <td>= 31,50</td> <td>31,50</td> </tr> <tr> <td>Barrel</td> <td>= 135,40</td> <td>142,50</td> </tr> <tr> <td>Plunger</td> <td>= 150,60</td> <td>150,20</td> </tr> <tr> <td>Plunger + Gasket</td> <td>= 154,10</td> <td>153,80</td> </tr> </tbody> </table>		Type 1	Type 2	Ø inside	= 28,70	28,70	Ø outside	= 31,50	31,50	Barrel	= 135,40	142,50	Plunger	= 150,60	150,20	Plunger + Gasket	= 154,10	153,80
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Luer Type and Conical Fitting (centric)	TS EN ISO 7886-2	%	Luer Lock – 6% Luer																		
Minimum Length Between Barrel and Plunder	TS EN ISO 7886-2 TS EN ISO 7886-1	mm	Not less than 8																		
Length of Scale	TS EN ISO 7886-2 TS EN ISO 7886-1	mm	Not less than 75																		
Scale Intervals	TS EN ISO 7886-2 TS EN ISO 7886-1	ml	1																		
Increment between Graduation Lines to be Numbered	TS EN ISO 7886-2 TS EN ISO 7886-1	ml	10																		
Patency of Lumen	TS EN ISO 7864	mm	Comply with standard (0,8 mm)																		
Lubricant	TS EN ISO 7886-2 TS EN ISO 7886-1 TS EN ISO 7864	mg/cm <sup>3</sup>	Max 0,25 polydimethylsiloxane																		
Plunger Stopper	AYSET	-	Latex Free																		
Opaque	AYSET	-	Opaque																		
Resistance to Pressure	TS EN ISO 7886-2	-	Resistant																		
Cleanliness	TS EN ISO 7864	-	Free from feather edges, burrs and hooks																		
Stiffness	DIN 13097	gr	Comply with standard																		
Weight	AYSET	gr	<table border="1"> <thead> <tr> <th>Type 1</th> <th>Type 2</th> </tr> </thead> <tbody> <tr> <td>34,00 - 34,70</td> <td>37,50 – 38,00</td> </tr> </tbody> </table>	Type 1	Type 2	34,00 - 34,70	37,50 – 38,00														
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Air Leakage during aspiration	TS EN ISO 7886-2 TS EN ISO 7886-1	kPa/sec.	No leakage at 88 kPa vacuum and 60 second																		
Liquid leakage under compression	TS EN ISO 7886-2 TS EN ISO 7886-1	kPa/sec.	No leakage at 300 kPa pressure and 30 second																		
Flow Rate Through the Needle	TS EN ISO 7886-2	-	<table border="1"> <thead> <tr> <th>Nominal Capacity of the Syringe, V ml</th> <th>Flow Rates ml/hour</th> <th>Start-up Time min</th> <th>Analysis period min</th> </tr> </thead> <tbody> <tr> <td>10≤V</td> <td>5</td> <td>30</td> <td>60 minus parking position</td> </tr> </tbody> </table>	Nominal Capacity of the Syringe, V ml	Flow Rates ml/hour	Start-up Time min	Analysis period min	10≤V	5	30	60 minus parking position										
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Plunger Forces Flow Rate	TS EN ISO 7886-2	-	<table border="1"> <thead> <tr> <th rowspan="2">Nominal Capacity of the Syringe, V ml</th> <th colspan="3">Flow Rate ml/hour</th> </tr> <tr> <th>Low</th> <th>Medium</th> <th>High</th> </tr> </thead> <tbody> <tr> <td>V≥50</td> <td>1</td> <td>50</td> <td>100</td> </tr> </tbody> </table>	Nominal Capacity of the Syringe, V ml	Flow Rate ml/hour			Low	Medium	High	V≥50	1	50	100							
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Compatibility of Syringe	TS EN ISO 7886-2	-	<table border="1"> <tr> <th rowspan="3">Nominal Capacity of the Syringe, V ml</th> <th colspan="5">Test Pressure kPa*</th> </tr> <tr> <td>7</td> <td>40</td> <td>70</td> <td>90</td> <td>133</td> </tr> <tr> <th colspan="5">Maximum displacement volume ml</th> </tr> <tr> <td>V≥50</td> <td>0,40</td> <td>1,20</td> <td>1,50</td> <td>1,80</td> <td>2,10</td> </tr> <tr> <td colspan="6">** 1 kPa= ~7,5 mmHg = ~0,145 lbf/in<sup>2</sup> (psi).</td> </tr> </table>	Nominal Capacity of the Syringe, V ml	Test Pressure kPa*					7	40	70	90	133	Maximum displacement volume ml					V≥50	0,40	1,20	1,50	1,80	2,10	** 1 kPa= ~7,5 mmHg = ~0,145 lbf/in <sup>2</sup> (psi).					
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<b>CHEMICAL PROPERTIES</b>																															
Neutrality	TS EN ISO 7886-2 TS EN ISO 7886-1 TS EN ISO 7864	pH	Difference less than 1																												
Pb, Zn, Sn, Fe	TS EN ISO 7886-2 TS EN ISO 7886-1 TS EN ISO 7864	mg/L	Totally less than 5																												
Cd	TS EN ISO 7886-2 TS EN ISO 7886-1 TS EN ISO 7864	mg/L	Less than 0,1																												
Corrosion	TS EN ISO 9626	-	No corrosive effect																												
Ethylene Oxide Residue	TS 9897	mg/L	Less than 5																												
<b>BIOLOGICAL PROPERTIES</b>																															
Bacterial Endotoxin (lal)	European Pharmacopoeia Chapters 9 2.6.14	IU/ml	Less than 0,125 den																												
Toxicity	TS EN ISO 10993-11	-	Nontoxic																												
Sterility	TS EN 556-1, TS 10409	-	Sterile																												
Hemolytic Effect	TS EN ISO 10993-4	-	No hemolytic effect																												
Cytotoxicity	EN ISO 10993-5	-	No cytotoxicity effect																												
Sensitivity	EN ISO 10993-10	-	No sensitivity																												
Irritation	EN ISO 10993-10	-	No irritation effect																												
<b>PACKAGING AND STORAGE</b>																															
Unit Packaging	TS EN ISO 7886-2 TS EN ISO 7886-1 TS EN ISO 7864	-	Transparent film + blister packaging from the medical paper and unit packaging shall be marked with the following information: name and address of the manufacturer, syringe capacity, date of manufacture, expiry date, lot number, reference number, needle size, sterile, apyrogenic and nontoxic, luer tip type, method of sterilization, easy opening direction of the package, a warning "Do not use if package is damaged" The syringe and hypodermic needle shall be packed in a unit packaging.																												
Secondary Packaging/Inner Box	TS EN ISO 7886-2 TS EN ISO 7886-1 TS EN ISO 7864	-	60 pcs. in inner box, microwave cardboard, offset printed box and secondary packaging shall be marked with following information: name and address of the manufacturer, syringe capacity, date of manufacture, expiry date, lot number, reference number, needle size, and the quantity of the box.																												
User Packaging/Carton Box	AYSET	-	6 inner boxes are put in carton boxes. User packaging shall be marked with the following information: name and address of the manufacturer, syringe capacity, date of manufacture, expiry date, lot number, reference number, needle size, and the quantity of the carton box.																												
Storage Conditions	AYSET	-	Kept away from direct sun light and stored in a clean and dry storage areas at max. 45 °C																												

<b>DISTRIBUTION:</b> Responsible Man. Quality Control Dept. Marketing Dept.		<b>PREPARED BY</b>	<b>CONFIRMED BY</b>
	<b>NAME - SURNAME</b>	Ömer DEĞİRMENCİOĞLU	Özgül UYAN
	<b>TITLE</b>	Quality Control Manager	Responsible Manager
	<b>DATE</b>	05.07.2021	05.07.2021
	<b>İMZA</b>		