

## TECHNICAL DATA SHEET

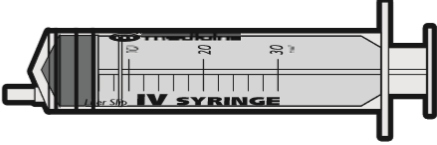

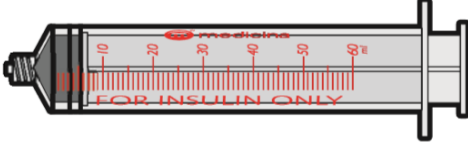
### INTRAVENOUS SYRINGES

November 2019

<b>Product Name</b>	Luer Lock IV Syringe (IVL) Luer Slip IV Syringe (IVS)		
<b>Product Range</b>	IVL01, IVL03, IVL05, IVL10, IVL20, IVL30, IVL60, IVL60 (INS). IVS01, IVS03, IVS05, IVS10, IVS20, IVS30, IVS60, IVS01 (INS), IVS10E.		
<b>Manufacturer</b>	Medicina Ltd Units 1-4 Rivington View Business Park Station Road, Blackrod Bolton BL6 5BN		
<b>Intended Use</b>	<p><b>Luer Lock IV Syringe (IVL)</b> - Single Use Sterile Luer lock IV syringes for use with IV extension sets, standard or safety needles, and IV cannula. They are also designed to be used on the most common types of syringe drivers.</p> <p><b>Luer Slip IV Syringe (IVS)</b> - Single Use Sterile Luer Slip IV syringes can be used together with hypodermic needles, and are intended to be used intravenously, to deliver drugs or take blood from the patient.</p>		
<b>Product Material Composition</b>	<b>Barrel &amp; Plunger</b>	Polypropylene (PP)	
	<b>Piston</b>	Poly-Isoprene (Latex Free)	
	<b>Lubricant</b>	High Grade Silicone Oil	
<b>Classification</b>	Class IIa		
<b>Conformity Assessment Route</b>	MDD 93/42/EEC, Annex V, Rule 2		
<b>Notified Body</b>	SGS 0120		
<b>Certificate Ref</b>	GB12/84913		
<b>Shelf Life</b>	5 Years		
<b>Lot Number format</b>	YYMMDD – XX (Where Y is Year, M is Month, D is Date) (X is product size)		
<b>Storage</b>	To be stored at a minimum of 5°C and a maximum of 35°C with a maximum relative humidity of 80%.		
<b>Appearance</b>	<b>General</b>	All components (product, pouches, and boxes) should be free of damage, no tears or holes.	
	<b>Product Blister</b>	Shall contain individually packed syringe.	
	<b>Inner Box</b>	White inner box containing secondary packaging	
	<b>Shipping Carton</b>	Brown Shipping Carton Should be free of any major damage.	
	<b>Syringe</b>	Syringe free from defects; fins, burrs, plastic flow and material shortage.	
		Syringe barrel shall be transparent to see fiducial line clearly. Syringe Barrel with accurate readable graduations and no smearing	
		All print should be legible and clearly seen.	
<b>Piston</b>	Plunger will be attached to black piston and shall be intact.		
	<p>Shall be free from blooming and foreign matters. The surface shall be free from cracks, cutting, damage and uneven surfaces.</p> <p>Outer diameter of the piston shall be equal or shorter than the outer diameter of the piston sealing ring.</p>		

<b>Labelling and Symbols</b>	<b>Label Information</b>	Shall match the copies in artwork master file.			
	<b>Symbols</b>	Shall match the copies in artwork master file.			
<b>Product Packaging Material Composition</b>	<b>Blister Packaging</b>	Paper Layer: 100% Whole virgin wood pulp Blister: Polyethylene terephthalate (PET)+ Polyethylene (PE)			
<b>Blister Packaging Performance</b>	<b>Seal Dimension</b>	Seal line will be fully sealed. Heat sealed blister with seal width no less than 4mm $\pm$ 1 mm width on all sides.			
	<b>Seal strength</b>	Tested as per BS EN 868-5 tested on a 15 mm sample should be > 1.5 N			
	<b>Leak test performed on Blister</b>	Detecting seal leaks in porous packages by dye penetration according to YY/T 0681.4-2010.			
<b>Sterility</b>	<b>Method</b>	Ethylene Oxide (ETO) sterilised			
	<b>Re-sterilisation</b>	Device should not be re-sterilised			
	<b>ETO Residuals</b>	ETO residuals Shall be $\leq$ 10ug/ml			
	<b>Pyrogen</b>	Product free from pyrogen			
<b>Chemical Performance</b>	<b>pH Value</b>	pH Value difference between extract and blank solution shall not exceed 1.0 pH Extract solution: Purified water + Sample. Blank Solution: Purified water. Note, the quantity of extract solution is based on the nominal capacity of the syringe			
	<b>Readily Oxidizable substance</b>	The syringe extract solution and equal volume of blank solution to indirect titrations as per Standard GB/T14233.1, the amount of $KMnO_4$ consumption shall not exceed 0.5ml.			
<b>Physical Performance</b>	<b>Conical Fitting</b>	No Evident rocking or movement. Shall comply with ISO 594.			
	<b>Leakage</b>	There shall be no air leakage when syringe is under negative pressure 88Kpa for 60s + 5s at the contacting position between barrel and piston. The piston will not detach from plunger.			
	<b>Capacity Tolerance</b>	<b>Nominal capacity of syringe, V (ml)</b>	<b>Tolerance on graduated capacity</b>		<b>Maximum Dead Space (ml)</b>
			<b>Less than half nominal capacity</b>	<b>Equal to or greater than half nominal capacity</b>	
		V < 2	$\pm(1.5\%$ of V + 2% of expelled volume)	$\pm$ 5% of expelled Volume	0.07
		2 $\leq$ V < 5	$\pm(1.5\%$ of V + 2% of expelled volume)	$\pm$ 5% of expelled Volume	0.07
		5 $\leq$ V < 10	$\pm(1.5\%$ of V +1% of expelled volume)	$\pm$ 4% of expelled Volume	0.075
		10 $\leq$ V < 20	$\pm(1.5\%$ of V +1% of expelled volume)	$\pm$ 4% of expelled Volume	0.1
		20 $\leq$ V < 30	$\pm(1.5\%$ of V +1% of expelled volume)	$\pm$ 4% of expelled Volume	0.15
30 $\leq$ V < 50		$\pm(1.5\%$ of V +1% of expelled volume)	$\pm$ 4% of expelled Volume	0.17	
50 $\leq$ V	$\pm(1.5\%$ of V +1% of expelled volume)	$\pm$ 4% of expelled Volume	0.20		

<b>Sliding Performance</b>	<b>Nominal Capacity of syringe, V (ml)</b>	<b>Initial Force, F<sub>s</sub> Max (N)</b>	<b>Mean Force, F Max (N)</b>	<b>Maximum Force F Max (N)</b>	<b>Minimum Force, F Min (N)</b>
	V < 2	10	5	(2,0 measured ) or (measured+1,5N), whichever is higher	(0,5 measured ) or (measured-1,5N), whichever is the lower
	2 ≤ V < 50	25	10	(2,0 measured ) or (measured +1,5N), whichever is higher	(0,5 measured ) or (measured-1,5N), whichever is the lower
	50 ≤ V	30	15	(2,0 measured ) or (measured +1,5N), whichever is higher	(0,5 measured ) or (measured-1,5N), whichever is the lower
When syringe is filled with water up to its nominal capacity and kept vertically, the plunger shall not be moved by its own weight.					
<b>Graduation Lines</b>	<b>Variable Size (when X is replaced by product code)</b>		<b>Max Division value</b>	<b>Max Increment of numbering</b>	
	xxx01		0.1	0.01	
	xxx03		0.5	0.1	
	xxx05		1	0.2	
	xxx10		1	0.2	
	xxx20		5	1	
	xxx30		10	1	
	xxx60		10	1	
<b>Product Inclusions</b>	<b>Latex</b>	This product is free from Latex			
	<b>Phthalates</b>	This product is free from Phthalates			
	<b>Animal Derived Substances</b>	This product is free from Animal Derived Substances			
	<b>Bis Phenol A</b>	This product is free from Bis Phenol A			
	<b>Asbestos</b>	This product is free from Asbestos			
	<b>PCB's</b>	This product is free from PCB's			
<b>Product Disposal</b>		The user must follow the legal regulations and national codes of practice regarding disposal of hospital waste.			

<b>Representative Product Images</b>	<b><u>Luer Slip Syringe (IVS)</u></b>  <p>A Luer Slip Syringe (IVS) with a black plunger and a clear barrel. The barrel has markings for 10, 20, and 30 mL. The text 'm medicina' is at the top and 'IV SYRINGE' is at the bottom.</p>
	<b><u>Luer Slip Syringe IVS01 (INS)</u></b> No image available
	<b><u>Luer Lock Syringe (IVL)</u></b>  <p>A Luer Lock Syringe (IVL) with a black plunger and a clear barrel. The barrel has markings for 10, 20, and 30 mL. The text 'm medicina' is at the top and 'IV SYRINGE' is at the bottom.</p>
	<b><u>Luer Lock Insulin Syringe IVL60 (INS)</u></b>  <p>A Luer Lock Insulin Syringe (IVL60) with a black plunger and a clear barrel. The barrel has markings for 10, 20, 30, 40, 50, and 60 units. The text 'm medicina' is at the top and 'FOR INSULIN ONLY' is at the bottom.</p>