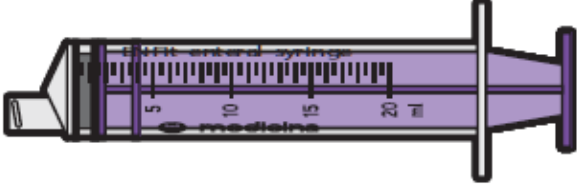


TECHNICAL DATA SHEET

Name	ENFit Home Syringe				
Product Code	LHExx (Non-Sterile)				
Shelf Life	5 Years				
Lot Number format	HMYyxxx (Y is for year, xxx is a sequential batch number)				
Expiry and Manufactured date format	YYYY/MM				
Appearance	General	All components (product, Bag, and boxes) should be free of damage, no tears or holes.			
	Blister	Product is provided in a single blister pack.			
	Box	White box with print shall be free of any major damage.			
	Outer Carton	Shipping carton shall be free of any major damage.			
	Syringe	Foreign matter under 30001x – 7001x Illuminance. Free from foreign particles and matters.			
		Syringe free from defects; fins, burrs, plastic flow and material shortage.			
		Syringe barrel shall be transparent to see fiducial line clearly. Syringe Barrel shall be legible with clear and even lines.			
		All print should be legible and clearly seen.			
		Plunger will be attached to black piston and shall be intact.			
	Piston	Shall be free from blooming and foreign matters. The surface shall be free from cracks, cutting, damage and uneven surfaces.			
Outer diameter of the piston shall be equal or shorter than the outer diameter of the piston sealing ring.					
Labelling and Symbols	Label Information	Shall match the copies in artwork master file.			
	Symbols	Shall match the copies in artwork master file.			
Material Composition	Barrel, Plunger & Tip	Polypropylene.			
	Piston	Silicone Rubber (Latex-Free)			
	Lubricant	Silicone Oil.			
Packaging	Bag	Multiple package (see table below). QML (minimum delivery quantity): 1 Box			
		PRODUCT CODE	CAPACITY	BOX CONTENT	CARTON CONTENT
		LHE01LD	1ml (low-dose)	100	2400
		LHE25LD	2.5ml (low-dose)	100	2000
		LHE05	5ml	100	1600
		LHE10	10ml	100	1000
		LHE20	20ml	80	800
		LHE30	30ml	80	640
		LHE60	60ml	60	240
		LHE100	100ml	30	120

Chemical Performance	pH Value	pH Value difference between extract and blank solution shall not exceed 1.0 pH <ul style="list-style-type: none"> • Extract solution: Purified water + Sample. • Blank Solution: Purified water. Note, the quantity of extract solution is based on the nominal capacity of the syringe.			
	Readily Oxidisable substance	The syringe extract solution and equal volume of blank solution to indirect titrations as per Standard GB/T14233.1, the amount of KM_nO_4 consumption shall not exceed 0.5ml.			
	IR Spectra	The spectra of the syringe materials correspond to the reference spectra.			
Physical Performance	Conical Fitting	No evident shaking or movement between standard gauge and conical fitting as per ISO 594.			
	Leakage	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.			
	Capacity Tolerance	Nominal capacity of syringe, V ml	Tolerance on graduated capacity		Maximum Dead Space ml
			Less than half nominal capacity	Equal to or greater than half nominal capacity	
		V < 2	±(1.5% of V + 2% of expelled volume)	± 5% of expelled Volume	0.07
		2 ≤ V < 5	±(1.5% of V + 2% of expelled volume)	± 5% of expelled Volume	0.07
		5 ≤ V < 10	±(1.5% of V +1% of expelled volume)	± 4% of expelled Volume	0.075
		10 ≤ V < 20	±(1.5% of V +1% of expelled volume)	± 4% of expelled Volume	0.10
		20 ≤ V < 30	±(1.5% of V +1% of expelled volume)	± 4% of expelled Volume	0.15
30 ≤ V < 50		±(1.5% of V +1% of expelled volume)	± 4% of expelled Volume	0.17	
50 ≤ V	±(1.5% of V +1% of expelled volume)	± 4% of expelled Volume	0.20		
Sliding Performance	Nominal Capacity of syringe, V ml	Initial Force, Fs Max. N	Mean Force, F Max N	Maximum Force F Max N	Minimum Force, F min N
	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.	
Product Drawing		
Product Inclusions	Latex	This product is free from Latex
	Phthalates	This product is free from Phthalates
	Animal Derived Substances	This product is free from Animal Derived Substances
	Bis Phenol A	This product is free from Bis Phenol A
	Asbestos	This product is free from Asbestos
	PCB's	This product is free from PCB's
Storage	To be stored at a minimum of 5°C and a maximum of 35°C with a maximum relative humidity of 80%.	
Disposal	The user must follow the legal regulations regarding disposal of hospital waste.	
Manufacturer	Medicina Ltd Units 1-4 Rivington View Business park Station Road, Blackrod Bolton BL6 5BN UK	
Classification	Class IIa Annex V & VII	
Conformity Assessment Route:	MDD 93/42/EEC	