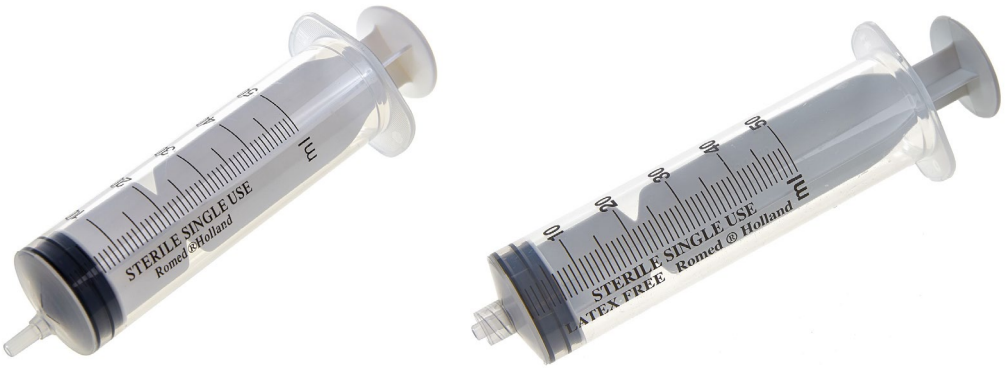
SPECIFICATIONS
ROMED STERILE SYRINGES FOR SINGLE USE
LATEX FREE, 50 ML
REF: 3SYR-50ML, 3S-50-LL



Applicable harmonized standard: EN ISO 7886-1:1997
Medical device conform MDD 93/42/EEC

Name of the product:
ROMED sterile syringes for single use

Product characteristics

Barrel	Polypropylene (PP)
Plunger	Polypropylene (PP)
Piston	Isoprene, Latex-Free

Volume: 50 ml

REF	Tip type	Tip position	Inner diameter	Graduation
3SYR-50ML	Luer Slip	Eccentric	29.29 mm	1 ml
3S-50-LL	Luer Lock	Concentric	29.3 mm	1 ml

REF	Length of barrel	Length of plunger	Size of rubber piston	Overall length
3SYR-50ML	129.5 mm	134.96 mm	11.85 mm	149.37 mm
3S-50-LL	126.83 mm	134.96 mm	11.85 mm	148.48 mm

Product is phthalates and latex-free

Syringes are not resistant to UV radiation.

Tooling parameters for raw materials:

Limit for extractable metals	:	Total ≤ 5 μg/ml, CD ≤ 0.1 μg/ml
Limits for acidity or alkalinity	:	△ pH ≤ 1 pH
Oxidized material	:	$KMnO_4$ consumption ≤ 0.5 ml

Method of sterilization : EO gas
Non-toxic, non-pyrogenic

The product is injection moulded with PP a three-piece structure (barrel, plunger, piston). The luer nozzle is situated either centrally or eccentrically.

If the single package is opened before use, discard it immediately and do not use it. Take care not to contaminate the product during unpacking. Assemble the injector with the syringe, suck a given amount of desired infusion, remove air and inject. The product is limited for single use and after use it must be discarded immediately.

The product remains sterile for a period of 5 years after sterilization, provided that it is kept under specified storage conditions. Do not use after expiry date.

Inspection item	**Technical requirements**
Tightness of injector body	No liquid leakage under 300 kPa pressure and 1.0 N action force for 30 seconds
Air tightness of suction	No air leakage under 88 kPa negative pressure for 60 ± 5 seconds, no separation of plunger
Error in capacity	Max. error of capacity ± 5% when above ½ main nominal mark line
Tightness of conical head	No water dropping under 300 kPa water pressure for 30 seconds, no continuous air bubble during suction
Separation force of conical head	No separation of the under-test inner conical head under 25 N reversed force
Sleeve length	At least 10% more than the length for the nominal capacity
Handle interval	≥ 9.0 mm
Requirements on conical head	≥ 1.2 mm, coaxial of sleeve with head-middle type injector
Dimensions of conical head	conforming to ISO 7886-1:1993
Flanging	no turning over in a place inclined at 10° with the level
Scale	Length ≥ 27 mm, middle deviation type injector keeping at opposite side of conical head
Graduation mark	Graduation 0.2 mm or 0.1 mm, evenly separated, flushing of marks for same volume, length of secondary mark ½ of that of main mark
Position of zero mark	Aligning with base line of piston, error ≤ ¼ graduation interval
Appearance	Free of flash, burr, sagging, defects, clean surface free of foreign matters, transparent sleeve, base line visible
Slippage	Good slippage, meeting requirements on pull or push force
Residual amount	≤ 0.07 ml

Packing
3SYR-50ML: Per piece in sterile blister, 25 pcs in an inner box: 16 inner boxes in an export carton
3S-50-LL: Per piece in sterile blister, 25 pcs in an inner box, 16 inner boxes in an export carton