

SPECIFICATIONS
ROMED STERILE SYRINGES FOR SINGLE USE
REF: 3SYR200ML-LT, 3SYR200ML-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

REF: 3SYR200ML-LT, 3SYR200ML-LL

Product characteristics

Barrel:	Polypropylene (PP)
Plunger:	Polypropylene (PP)
Piston:	Rubber, with small portion latex
Inner diameter:	45 mm
Graduation:	10 ml
Length of barrel	197mm
Length of plunger	181 mm
Size of rubber piston	18 mm
Overall length	216 mm

Product is phthalates free

Syringes are not resistant to UV radiation.

Tooling parameters for raw materials:

Limit for extractable metals	: Total $\leq 5 \mu\text{g/ml}$, CD $\leq 0.1 \mu\text{g/ml}$
Limits for acidity or alkalinity	: $\Delta \text{pH} \leq 1 \text{ pH}$
Oxidized material	: KMnO_4 consumption $\leq 0.5 \text{ ml}$

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

The product is injection moulded with PP in a three-piece structure. The product is assembled by outer barrel plunger with piston. The luer with catheter tip (LT) or luer lock (LL) is situated centrally.

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.

Packing

Per piece in sterile one pack, 10 pcs in an inner box, 10 inner boxes in an export carton