

SPECIFICATIONS
ROMED STERILE SYRINGES WITH BY-PACKED NEEDLE
FOR SINGLE USE
REF: SYR2ML-N, SYR5ML-N, SYR10ML-N, SYR20ML-N



Applicable harmonized standard: EN ISO 7886-1:1997, EN ISO 7864:1995
Medical device conform MDD 93/42/EEC

Name of the product

ROMED sterile syringes for single use, 3-part with by-packed needle
 SYR2ML-N 2ml syringe with 23Gx1 needle, concentric tip
 SYR5ML-N 5ml syringe with 21Gx1.5 needle, concentric tip
 SYR10ML-N 10ml syringe with 21Gx1.5 needle, concentric tip
 SYR20ML-N 20ml syringe with 21Gx1.5 needle, eccentric tip

Materials

Syringes

Barrel : PP
 Plunger : PP
 Piston : Latex free rubber
 Sizes : 2 ml, 5 ml, 10 ml, 20 ml

Needles

Hub and protector : PP
 Cannula : Stainless steel

Needles are coated with silicone to have good sharpness and for protection of the needle.

All materials used are medical class.

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 $\leq 0.5 \text{ ml}$

Dimensions

Content	Graduation	Inner Diameter	Needle size (G x inch)	Needle size (mm x mm)
2 ml	0.1 ml	8.80 mm	23Gx1	0.6 x 25
5 ml	0.1 ml	12.4 mm	21Gx1.5	0.8 x 40
10 ml	0.2 ml	14.95 mm	21Gx1.5	0.8 x 40
20 ml	0.5 ml	19.20 mm	21Gx1.5	0.8 x 40

Product specification		2 ml	5 ml	10 ml	20 ml
Syringe length (mm)	without needle	70.0 ± 1.0	84.0 ± 1.0	104.0 ± 1.0	121.0 ± 1.0
	with needle	110.0 ± 1.5	136.0 ± 1.5	155.0 ± 1.5	174.0 ± 1.5

Use

This product is intended to be used for hypodermic injection and fluid drawing. The syringe is injection moulded. The by-packed needle includes a hub with stainless steel cannula and a protection cap. The needle can be fixated on the luer nozzle of the syringe on which 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.

Sterilization

Method of sterilization : EtO gas

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

SYR2ML-N: Per set in sterile blister, 100 pieces in an inner box, 30 inner boxes in an export carton
SYR5ML-N: Per set in sterile blister, 100 pieces in an inner box, 24 inner boxes in an export carton
SYR10ML-N: Per set in sterile blister, 100 pieces in an inner box, 16 inner boxes in an export carton
SYR20ML-N: Per set in sterile blister, 50 pieces in an inner box, 16 inner boxes in an export carton