

SPECIFICATIONS
ROMED TUBERCULIN SYRINGES WITH MOUNTED NEEDLE AND
INSULIN SYRINGES WITH INTEGRATED NEEDLE FOR SINGLE USE
LATEX-FREE
REF: 3TS-1ML, 3IS-1ML



Applicable harmonized standard: EN ISO 7886-1:1997, EN ISO 7864:1995, EN ISO 8537:2008
Medical device conform MDD 93/42/EEC

Name of the product

ROMED 3-part tuberculin syringe with mounted needle, sterile, for single use (Ref: 3TS-1ML)
 ROMED 3-part insulin syringe with integrated needle, sterile, for single use (Ref: 3IS-1ML)

Product characteristics

Needle
 Hub and protector : Medical class polypropylene
 Cannula : Stainless steel
 Size : 29Gx1/2 (0.33 x 13 mm)

Syringes are not resistant to UV radiation.

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

Syringes
 Material barrier : Polypropylene (PP)
 Plunger : Polypropylene (PP)
 Piston : Isoprene (Latex-Free)
 Sizes : 1 ml
 Graduation 3TS-1ML : 0.02 ml
 Graduation 3IS-1ML : 0.025 ml

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 : EtO gas
Non-toxic, non-pyrogenic

This product is intended to be used for hypodermic injection and fluid drawing.

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. 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.

Product is phthalates and latex-free.

Packing

Per piece in sterile blister packing, 100 pieces in an inner box, 32 inner boxes in an export carton