TECHNICAL DATA SHEET

TE78315 SlimTube 2 ml

PRODUCTION

TENAK SlimTube is designed and manufactured in Denmark.
The raw materials comply with applicable regulations and standards.
The production takes place in clean room environment.

QUALITY MANAGEMENT SYSTEM

The production is GMP oriented.
Certified ISO 9001:2008.
Fulfills the criteria of medical devices according to European Directive 93/42/ECC.

BIOLOGICAL SAFETY

Made of polypropylene (PP).

- Non-cytotoxic according to ISO 10993-5, UPS 312008 test.
- Without stripping agents, softeners, and heavy metals.
- Without detectable DNA/RNA and ATP.
- Without detectable DNase/RNase.
- Does not contain substances of animal origin and is therefore without TSE/BSE
- Without detectable endotoxins (pyrogens).

The product is sterilised, and this process is validated according to ISO 11137-2:2013.

- Sterility Assurance Level (SAL) 10^{-6}
- The product is intended for single use only.

Colourings do not contain heavy metals.
Packaging materials do not contain heavy metals.

QUALITY CONTROL

Quality test is performed and approved by Danish Technological Institute.
All products are subject to visual and measurement control when passing through the production line, and are visually inspected before packing.
Quantity is electronically counted and controlled by check weighing.
Leakage test is performed for each batch.
Lot number is printed on each product pouch and case label.

STORAGE

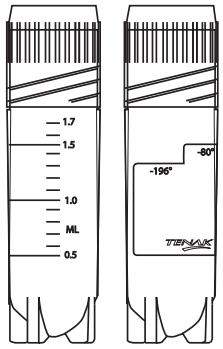
The expiration date is 5 years from date of sterilisation.
Storage recommendations:

- Relative humidity max. 50-60%.
- Temperature 10-30 °C (50-86 °F).
- Do not expose to direct sunlight.

CERTIFICATIONS AND COMPLIANCE

CE marked for storage of in vitro diagnostic samples.
Meets all the provisions on in vitro diagnostic medical devices 98/79/EC Directive DS EN144254 + DS EN14820.

SPECIFICATIONS



External diameter: 12,08 mm

Height: 47,6 mm

Net weight of the product: 1,7 g

Package: 10 x 100/pk

Labelled

Sterile

Starfoot

Carton External Dimentions:
384 x 252 x 140 mm

Net Weight: 2300 g

TENAK A/S. Skelstedet 2B
DK-2950 Vedbaek, Denmark
Tel. +45 88 20 20 70
E-mail: info@tenak.com
Fax. +45 88 20 20 79
www.tenak.com