



Product

TRANSONIC® STERILE GEL

Ultrasound transmission gel

Date

December 2019

References

G-15E

Specification N.

ETP/208/10



TECHNICAL SPECIFICATIONS

Ingredients

- Aqua (water), propylene glycol, carbomer, diazolidinyl urea, methylparaben, propylparaben, disodium EDTA.

Materials

- Gel composition: Water-based gel with polymers.
- Packaging:
 - Sachet: PET/Pet-metalized/PE film
 - Thermo-sealed pouch:
 - Cellulose paper, medical grade
 - Transparent PA/PP film



Physico-chemical properties

- Colour, Odour, Appearance: Colourless or slightly yellowish, transparent and viscous gel. Odour to its raw materials (it does not contain perfume).
- Density: 1.00 – 1.02 g/mL.
- pH: 5.8 – 6.1.
- Viscosity (Brookfield, LVT, h.4, sp.0.3, factor 2000): 800.000 – 2.000.000 mPa·s.
- Acoustic impedance: 1.62MRayls.
- Efficiency (from 0.5MHz): >99.5%.

Microbiological properties

- Sterile according the normative EN 556-1 standard

Biocompatibility

- ISO 10993-5: No cytotoxic.
- ISO 10993-10: No sensitizing.
- ISO 10993-10: Negative intracutaneous irritation test.

Conclusion: The product is biocompatible.



Sterilization and expiry date

- Sterile product by radiation.
- Shelf life: 2 years upon manufacturing date.

Storage and maintenance

- Keep protected from direct sunlight / the outside.
- Keep in a dry place.
- Temperature range: 5-40°C.
- Single use product. No maintenance required.

Packaging

- Double packaging, monodose, 20 mL.
- 48 unit service box.

PRODUCT CHARACTERISTICS

- Does not irritate skin.
- Non greasy.
- Hydrosoluble.
- Does not contain salt. Does not damage the transducer.
- It spreads out easily and uniformly.
- This product is free to natural latex, phthalatos and animal or biological origin compounds.

USE INSTRUCTIONS

- Apply over the selected area.
- Remove using a disposable towel.

REGULATORY INFORMATION

TELIC, S.A.U. guarantees that this product is in conformity with **MDD 93/42/EEC** and that it has been manufactured following the directives of the Quality Assurance System certified as **ISO 13485**.

This product is classified as:

- **Class I sterile** product according to Annex IX of MDD 93/42/EEC, rule 1.
- GMDN code: 58735 – Coupling gel, sterile.
- UMDNS code: -1519 Ultrasonic Coupling Gel