

Conductive gel

Electro-gel

> Product description

Conductive gel for electromedical procedures (ECG, TENS).



> Product characteristics

- Highly conductive.
- Short and long term monitoring.
- Does not irritate the skin.
- Hydrosoluble.
- Non-greasy.
- Gel can be easily and uniformly spread.
- Does not damage terminals or contacts.

> Technical specifications

> Ingredients

Aqua (Water), Potassium Chloride, Propylene Glycol, Hydroxyethylcellulose, Magnesium Nitrate, Triethanolamine, Methylchloroisothiazolinone, Magnesium Chloride, Methylisothiazolinone, CI 42051

> Materials

- Cosmetic or pharmaceutical grade raw materials.
- Packaging: HDPE bottle with PP cap, suitable for food contact.

> Physio-chemical proprieties

- Colour, Odour, Appearance: Transparent viscous gel with blue-greenish colour.
Odour to its raw materials (does not contain perfume).
- Viscosity (22°C): 220.000 – 360.000 mPa·s
- pH: 6.7 – 7.5
- Density (22°C): 1.00 – 1.05 g/ml

> Electrical properties (ANSI/AAMI EC12)

- DC Offset voltage: <100mV
- AC Impedance 10Hz: <2000Ω
- Defibrillation overload recovery:
- ΔV <100mV
- ΔV/t <1mV/s
- AC Impedance 10Hz after defibrillation: <100mV
- Combined Offset instability and internal noise: <150μV
- Bias current tolerance 8h: <100mV

Conclusion: safety electrical requirements are met.

> Microbiological properties

- Total aerobes: <10 UFC/mL
- Moulds and yeasts: <10 UFC/mL
- Pathogens (Staphylococcus aureus, Candida albicans, Pseudomonas aeruginosa, Escherichia coli): Absence

> 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

- Non-sterile product.
- Shelf life: 3 years upon the manufacturing date.

> Storage and maintenance

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

> Packaging

#	Ref	Packaging
G-10	TOG01	250 ml bottle with dosing cap. Service box of 25 units.

> Instructions for use

- Apply on the selected area and remove with a disposable towel.

Date: January 2024

Specification N°: ETP/011/15

> Regulatory information

TELIC, S.A.U. guarantees that this product is in conformity with **Regulation (UE)2017/745** 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** product according to Annex VIII of Regulation (UE) 2017/745, rule 1
- GMDN code: 11425 Electrodes, gel.
- EMDN code: C020599 (Cardiac diagnostic Devices-other).