



Product

DORMO®
Disposable E.C.G. electrodes
Semiliquid Gel

References

LF-50	LF-36
LP-50	LEH-36
LR-50	

Date

February 2022

Specification N.

ETP/090/16

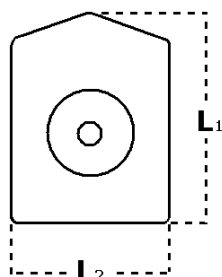
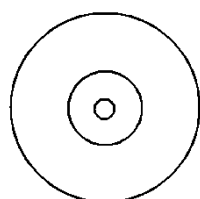
TECHNICAL SPECIFICATIONS

Materials

- Supporting materials
 - **LF-50, LF-36, LEH-36:** flexible PE foam (impermeable).
 - **LP-50:** non-woven breathable tissue.
 - **LR-50:** breathable twill.
- Adhesive: Acrylic
- Sensor: Stainless steel / Ag-AgCl coated plastic rivet
- Cover: PET
- Label: PET/PP Film
- Semiliquid gel: Hydrosoluble acrylic gel adsorbed on polyether foam
- Pouch: Cellulose / Aluminium / PE film



Main dimensional properties



Reference	Diameter (mm)	
	L ₁ (mm)	L ₂ (mm)
LF-50 LP-50 LR-50	50 ± 1	
LF-36	42 ± 1	36 ± 1
LEH-36	50 ± 1	36 ± 1



Biocompatibility

- ISO 10993-5: No cytotoxic
- ISO 10993-10: no sensitizing
- ISO 10993-10: negative intracutaneous irritation test

Conclusion: product is biocompatible

Sterility and expiry date

- Non sterile product
- Expiry date: 3 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. Disposable.
- Latex free

Packaging

- 50 units per pouch.
- 20 pouches per service box, 1000 units.

PRODUCT CHARACTERISTICS

Electric properties ANSI/AAMI EC12

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

Conclusion: safety electrical requirements are met

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: 35035 Electrocardiographic electrode, single-use.
- EMDN code: C020501 (ECG Electrodes).