

Medical Disposable EEG Sensor



1. Product Overview

- The VMANX Disposable EEG Sensor is engineered for clinical electroencephalography (EEG) monitoring.
- They feature a three-layer composite structure, manufactured through precision printing, die-cutting, and assembly processes.
- The product meets stringent requirements for high signal fidelity, biocompatibility, and electrical safety.
- It is suitable for use in operating rooms, ICUs, and for dynamic EEG monitoring scenarios.
- Complies with the ISO 13485 Medical Devices Quality Management System.



2. Structural Design

Layer	Material/Process	Function
Top Layer	Medical PET Film + Screen-Printed Ag Conductive Layer	Medical Foam Adhesive (ISO 10993 Certified)
Middle Layer	Silver/Silver Chloride (Ag/AgCl) Sensing Electrode	Stable biopotential conversion, reduced polarization
Base Layer	Medical Foam Adhesive (ISO 10993 Certified)	Skin adhesion, pressure dispersion, comfort

3. Key Technical Specifications

3.1 Electrical Performance

Parameter	Test Condition	Specification	Standard
AC Impedance	10Hz, electrode-skin interface	≤5 kΩ (Typ. ≤3 kΩ)	IEC 60601-2-26
DC Offset Voltage	200nA input bias current	≤±100 mV	ANSI/AAMI EC12
Internal Noise	0.5–100 Hz bandwidth	≤2 μVpp	IEC 60601-2-26
Defibrillation Recovery	Post 5kV defibrillation	Recovery time ≤10 sec	IEC 60601-2-26
Post-Defibrillation Voltage (30s)	Immediately after discharge	≤100 mV	IEC 60601-2-26
Bias Current Tolerance	±300 nA continuous input	Output drift ≤5%	ANSI/AAMI EC12

3.2 Safety & Reliability

Parameter	Specification	Standard
Biocompatibility	ISO 10993 Series Compliant	ISO 10993-5, -10
Cytotoxicity	Non-cytotoxic (Grade 0)	ISO 10993-5
Skin Sensitization	Compliant	ISO 10993-10
Dielectric Withstand	5000 VAC, 60s no breakdown	IEC 60601-1
Inter-Electrode Resistance	≤1 Ω	Internal Standard

4. Manufacturing & Quality Control	
▶ Electrode Printing	: High-precision screen printing, Ag layer thickness tolerance $\pm 5\mu\text{m}$
▶ Die-Cutting	: Laser-guided precision, electrode aperture accuracy $\pm 0.1\text{mm}$
▶ Assembly	: Class 100,000 cleanroom, ESD-controlled environment
▶ In-process Testing	: Batch sampling for impedance, peel adhesion, bioburden
▶ Sterilization	: Ethylene Oxide (EO), residuals $\leq 0.1\text{ppm}$ (ISO 11135)

5. Compliance & Certifications	
▶ Quality Management	: ISO 13485:2016 certified.
▶ Regulatory Compliance	: EU CE Mark (MDR 2017/745), US FDA 510(k) listed
▶ Environmental Standards	: RoHS 3.0, REACH SVHC compliant.

6. Packaging & Storage	
▶ Primary Package	: Sterile foil pouch, 1 sensor/pouch
▶ Labeling	: UDI-DI, Lot number, Expiry date
▶ Storage	: 15–30°C, <70% RH, avoid direct light
▶ Shelf Life	: 24 months (unopened)

7. Product Diagram

