



**Ministerio de Salud**  
República Argentina

2026 - AÑO DE LA GRANDEZA ARGENTINA

## **DECLARACION JURADA**

DISPOSICIÓN ANMAT N° 236/2026  
DECRETO 895/25

**N° rev: 2362-23#0001**

En nombre y representación de la firma Biotek Medical S.R.L. , el responsable legal y el responsable técnico declaran bajo juramento cumplir con la Disposición 236/26 para el producto médico declarado bajo el Número de PM: 2362-23

### **Datos Característicos del Producto Médico:**

Nombre descriptivo: Sensor de Oximetría SpO2

Código de identificación y nombre técnico del producto médico, (ECRI-UMDNS):  
17-594 Sondas, para Oxímetros

Marca(s) de (los) producto(s) médico(s): YKD

Regla de clasificación Disposición ANMAT N° 64/25: Regla 10

Clase de Riesgo: II

Indicación/es de uso: Medición no invasiva de la saturación de oxígeno en sangre (SpO2) y frecuencia de pulso, mediante el uso del sensor conectado a equipos compatibles.

Modelos: CSL040E; CSL037G; CSL037F; CSL037E; CSL037D; CSL037C; CSL037B; CSL097G;  
CSL097F; CSL097E; CSL097D; CSL097C; CSL097B; CSL036G; CSL039B; CSL039C;  
CSL040D; CSL040C; CSL088G; CSL040B; CSL088F; CSL088E; CSL088D; CSL088C;  
CSL088B; CSL039G; CSL039F; CSL039E; CSL039D; CSL036F; CSL036E; CSL043G; CSL043F;  
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CSL120E; CSL120D; CSL029F; CSL040F; CSL121F; CSL0127B; CSL0126G; CSL0126F;  
CSL0126E; CSL0126D; CSL0126C; CSL0126B; CSL129G; CSL129F; CSL129E; CSL129D;  
CSL129C; CSL129B; CSL0127C; CSL0127D; CSL121E; CSL121D; CSL121C; CSL121B;  
CSL0128G; CSL0128F; CSL0128E; CSL0128D; CSL0128C; CSL0128B; CSL0127G; CSL0127F;

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CSL046C; CSL046B; CSL045G; CSL045F; CSL045E; CSL040G; CSL084E; CSL099C;  
CSL099B; CSL098G; CSL098F; CSL098E; CSL098D; CSL098C; CSL098B; CSL083G;  
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CSL126C; CSL126B; CSL008G; CSL032B; CSL032C; CSL029D; CSL029C; CSL029B;  
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CSL119C; CSL119B; CSL118G; CSL118F; CSL118E; CSL118D; CSL084G; CSL121G; CA104J;  
CA017A; CA089M; CA063A; CA046G; CA088A; CA087A; CA045G; CA052A; CA051A; CA040A;  
CA085A; CA039A; CA035F; CA050A; CA090A; CA049A; CA112E; CA112K; CA111M; CA0103A;  
CA028M; CA012B; CA091C; CA057A; CA056A; CA048A; CA096A; CA047A; CA034F; CA101B;  
CA024A; CA060A; CA059A; CA076A; CA075A; CA072A; CA026A; CA022A; CA074A; CA073M;  
CA021A; CA058A; CA071H; CA025A; CA084C; CA110A; CA054A; CA061C; CA031A; CA029A;  
CA083M; CA082M; CA081B; CA080B; CA079B; CA078B; CA023A; CA077B; CA070C; CA105J;  
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CD001C; CD001B; CD001A; CA109B; CA108B; CA107B; CD003C; CD003D; CD006A; CD005D;  
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CSL059C; CSL059B; CSL015G; CSL015F; CSL015E; CSL015D; CSL015C; CSL015B;

CSL013G; CSL106B; CSL106C; CSL020D; CSL020C; CSL020B; CSL018G; CSL018F;  
CSL018E; CSL018D; CSL018C; CSL018B; CSL106G; CSL106F; CSL106E; CSL106D; CSL013F

Composición cuali-cuanti porcentual exacta (si corresponde): No Aplica

Período de vida útil: 5 años

Condición de uso: Uso exclusivo a profesionales e instituciones sanitarias

Contiene látex: NO

Forma de presentación: Por Unidad

Método de esterilización: No Aplica

Condición de conservación/almacenamiento (SI CORRESPONDE): Temperatura: -10 °C ~ + 40 °C; Humedad: 0% ~ 80%; Presión: 86 kPa ~ 106 kPa

Nombre del fabricante: SHENZHEN YKD TECHNOLOGY CO., LTD.

Lugar de elaboración: 6F, Building 6, Huaxinruiming Industrial Area, Langrong RD, Xinwei Village, Dalang Community, Dalang Street, Longhua, 518000 Shenzhen, CHINA.

El responsable legal y su responsable técnico son responsables de la veracidad de la documentación e información presentada y declaran bajo juramento que el producto médico, que cumple y satisface con los Requisitos Esenciales de Seguridad y Desempeño (R.E.S.D.) previstos por la Disposición ANMAT N° 11467/24.

La empresa mantiene en su establecimiento y a disposición de la autoridad sanitaria la documentación requerida por Disposición ANMAT N°236/26, Disposición ANMAT N°64/25 y Disposición ANMAT N° 9688/19.

Firma del Responsable Legal

Firme Responsable Técnico

La presente DECLARACIÓN JURADA ha sido emitida de acuerdo con las previsiones del Decreto 892/25 y la Disposición ANMAT N° 236/26, quedando en el Registro Nacional de Productores y Productos de Tecnología Médica (R.P.P.T.M.) a favor de Biotek Medical S.R.L. bajo el número PM 2362-23, siendo su vigencia hasta el 26 junio de 2031

La presente DJ será válida cuando sea escaneado su código QR y verificada digitalmente a través de la página de ANMAT. Asimismo, deberá estar acompañada de las disposiciones o DJ de habilitación enunciadas anteriormente.



La validez del presente documento deberá verificarse mediante el código QR.

N° Identificador Trámite: 79439

Tramitada por Expediente N°: 1-0047-3110-004956-26-4