



Ministerio de Salud
República Argentina

2026 - AÑO DE LA GRANDEZA ARGENTINA

DECLARACION JURADA

DISPOSICIÓN ANMAT N° 236/2026
DECRETO 895/25

N° rev: 2362-26#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: 2362-26

Datos Característicos del Producto Médico:

Nombre descriptivo: Cables para electrocardiografía

Código de identificación y nombre técnico del producto médico, (ECRI-UMDNS):
15-754 Cables/Terminales, para Electrocardiografía

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

Regla de clasificación Disposición ANMAT N° 64/25: Regla 1

Clase de Riesgo: I

Indicación/es de uso: Los cables para electrocardiografía (ECG) están indicados para conectar los electrodos aplicados al paciente con monitores de paciente, electrocardiógrafos u otros equipos compatibles, permitiendo la transmisión de las señales bioeléctricas cardíacas para su visualización, registro o monitoreo por el equipo conectado.

Modelos: G3101S; G3110S; G3119S; G3128S; G3141S; G3152S; G3102S; G3111S; G3120S; G3129S; G3142S; G3153S; G3103S; G3112S; G3121S; G3130S; G3143S; G3155S; G3104S; G3113S; G3122S; G3131S; G3144S; G3156S; G3105S; G3114S; G3123S; G3132S; G3145S; G3157S; G3106S; G3115S; G3124S; G3133S; G3146S; G31107S; G3107S; G3116S; G3125S; G3134S; G3147S; G3108S; G3117S; G3126S; G3135S; G3148S; G3109S; G3118S; G3127S; G3140S; G3149S; G3201S; G3210S; G3219S; G3228S; G3241S; G3252S; G3202S; G3211S; G3220S; G3229S; G3242S; G3253S; G3203S; G3212S; G3221S; G3230S; G3243S; G3255S; G3204S; G3213S; G3222S; G3244S; G3256S; G3205S; G3214S; G3223S; G3232S; G3245S; G3257S; G3206S; G3215S; G3224S; G3233S; G3246S; G32107S; G3207S; G3216S; G3225S;

G3234S; G3247S; G3208S; G3217S; G3226S; G3235S; G3248S; G3209S; G3218S; G3227S;
G3240S; G3249S; G4112S; G4212S; G5101S; G5110S; G5119S; G5128S; G5141S; G5152S;
G5102S; G5111S; G5120S; G5129S; G5142S; G53153S; G5103S; G5112S; G5121S; G5130S;
G5143S; G5155S; G5104S; G5113S; G5122S; G5131S; G5144S; G5156S; G5105S; G5114S;
G5123S; G5132S; G5145S; G5106S; G5115S; G5124S; G5133S; G5146S; 51107S; G5107S;
G5116S; G5125S; G5134S; G5147S; G5108S; G5117S; G5126S; G5135S; G5248S; G5109S;
G5118S; G5127S; G5140S; G5149S; G5201S; G5210S; G5219S; G5228S; G5241S; G5252S;
G5202S; G5211S; G5220S; G5229S; G5242S; G53253S; G5203S; G5212S; G5221S; G5230S;
G5243S; G5255S; G5204S; G5213S; G5222S; G5231S; G5244S; G5256S; G5205S; G5214S;
G5223S; G5232S; G5245S; G5206S; G5215S; G5224S; G5233S; G5246S; 52107S; G5207S;
G5216S; G5225S; G5234S; G5247S; G5208S; G5217S; G5226S; G5235S; G5209S; G5218S;
G5227S; G5240S; G5249S; G3101P; G3110P; G3119P; G3128P; G3141P; G3152P; G3102P;
G3111P; G3120P; G3129P; G3142P; G3153P; G3103P; G3112P; G3121P; G3130P; G3143P;
G3155P; G3104P; G3113P; G3122P; G3131P; G3144P; G3156P; G3105P; G3114P; G3123P;
G3132P; G3145P; G3157P; G3106P; G3115P; G3124P; G3133P; G3146P; G31107P; G3107P;
G3116P; G3125P; G3134P; G3147P; G3108P; G3117P; G3126P; G3135P; G3148P; G3109P;
G3118P; G3127P; G3140P; G3149P; G3201P; G3210P; G3219P; G3228P; G3241P; G3252P;
G3202P; G3211P; G3220P; G3229P; G3242P; G3253P; G3203P; G3212P; G3221P; G3230P;
G3243P; G3255P; G3204P; G3213P; G3222P; G3231P; G3244P; G3256P; G3205P; G3214P;
G3223P; G3232P; G3245P; G3257P; G3206P; G3215P; G3224P; G3233P; G3246P; G32107P;
G3207P; G3216P; G3225P; G3234P; G3247P; G3208P; G3217P; G3226P; G3235P; G3248P;
G3209P; G3218P; G3227P; G3240P; G3249P; G4112P; G4212P; G5101P; G5110P; G5119P;
G5128P; G5141P; G5152P; G5102P; G5111P; G5120P; G5129P; G5142P; G53153P; G5103P;
G5112P; G5121P; G5130P; G5143P; G5155P; G5104P; G5113P; G5122P; G5131P; G5144P;
G5156P; G5105P; G5114P; G5123P; G5132P; G5145P; G5106P; G5115P; G5124P; G5133P;
G5146P; G51107P; G5107P; G5116P; G5125P; G5134P; G5147P; G5108P; G5117P; G5126P;
G5135P; G5148P; G5109P; G5118P; G5127P; G5140P; G5149P; G5201P; G5210P; G5219P;
G5228P; G5241P; G5252P; G5202P; G5211P; G5220P; G5229P; G5242P; G53253P; G5203P;
G5212P; G5221P; G5230P; G5243P; G5255P; G5204P; G5213P; G5222P; G5231P; G5244P;
G5256P; G5205P; G5214P; G5223P; G5232P; G5245P; G5206P; G5215P; G5224P; G5233P;
G5246P; G52107P; G5207P; G5216P; G5225P; G5234P; G5247P; G5208P; G5217P; G5226P;
G5235P; G5248P; G5209P; G5218P; G5227P; G5240P; G5249P; G3101DN; G3103LL;
G3108DN; G3111DX; G3114LL; G3118DN; G3121DN; G3124AA; G3128DN; G3131LL;
G3134NH; G3140DN; G3142DN; G3145LL; G3148LL; G3152DN; G3101LL; G3104DN;
G3108LL; G3112DN; G3115DN; G3118LL; G3121NK; G3125DN; G3129DN; G3131DR;
G3134NK; G3140LL; G3142LL; G3145DT; G3149DN; G3155LL; G3101MD; G3104LL; G3108DR;
G3112LL; G3115MP; G3118MD; G3121NH; G3125LL; G3129LL; G3132DN; G3135DN;
G3140MD; G3143DN; G3146DN; G3149LL; G3101AA; G3105DN; G3109RD; G3112MQ;
G3116DN; G3119DN; G3122DN; G3126DN; G3130DN; G3132LL; G3135LL; G3141DN;
G3143MD; G3146LL; G3150DN; G3102DN; G3105LL; G3110DN; G3113DN; G3116MN;
G3119LL; G3123DN; G3126LL; G3130NK; G3133DN; G3141LL; G3144LL; G3147DN; G3150LL;
G3155DN; G3102LL; G3106CL; G3110DX; G3113LL; G3117DN; G3120DN; G3123AA;
G3127DN; G3130NH; G3133DR; G3141MD; G3145DN; G3147LL; G3152LL; G3156DN;
G3103DN; G3107CL; G3111DN; G3114DN; G3117MN; G3120LL; G3124DN; G3127LL;
G3131DN; G3134DN; G3148DN; G3153LL; G3157DN; G3153DN; G3156LL; G3202DN;
G3203LL; G3208DN; G3211DX; G3214LL; G3218DN; G3221DN; G3224AA; G3228DN;
G3231LL; G3234NH; G3240DN; G3242DN; G3245LL; G3248LL; G3252DN; G3201LL;
G3204DN; G3208LL; G3212DN; G3215DN; G3218LL; G3221NK; G3225DN; G3229DN;
G3231DR; G3234NK; G3240LL; G3242LL; G3245DT; G3249DN; G3255LL; G3201MD; G3204LL;
G3208DR; G3212LL; G3215MP; G3218MD; G3221NH; G3225LL; G3229LL; G3232DN;
G3235DN; G3240MD; G3243DN; G3246DN; G3249LL; G3201AA; G3205DN; G3209RD;

G3212MQ; G3216DN; G3219DN; G3222DN; G3226DN; G3230DN; G3232LL; G3235LL;
G3241DN; G3243MD; G3246LL; G3250DN; G3205LL; G3210DN; G3213DN; G3216MN;
G3219LL; G3223DN; G3226LL; G3230NK; G3233DN; G3248DN; G3241LL; G3244LL; G3256DN;
G3252LL; G3202LL; G3206CL; G3210DX; G3213LL; G3217DN; G3220DN; G3223AA;
G3227DN; G3230NH; G3233DR; G3241MD; G3245DN; G3247LL; G3256LL; G3253DN;
G3203DN; G3207CL; G3211DN; G3214DN; G3217MN; G3220LL; G3224DN; G3227LL;
G3231DN; G3234DN; G3247DN; G3250LL; G3255DN; G3257DN; G3253LL; G5101DN;
G5105LL; G5108DN; G5111DX; G5114LL; G5118DN; G5121DN; G5124AA; G5128DN;
G5151LL; G5154NH; G5140DN; G5142DN; G5145LL; G5148LL; G5152DN; G5201LL;
G5204DN; G5208LL; G5212DN; G5215DN; G5218LL; G5221NK; G5225DN; G5229DN;
G5251DR; G5254NK; G5240LL; G5242LL; G5245DT; G5249DN; G5101MD; G5104LL;
G5108DR; G5112LL; G5115MP; G5118MD; G5121NH; G5125LL; G5129LL; G552DN; G5155DN;
G5140MD; G5145DN; G5146DN; G5149LL; G5101AA; G5105DN; G5109RD; G5112MQ;
G5116DN; G5119DN; G5122DN; G5126DN; G5150DN; G5152LL; G5155LL; G5141DN;
G5145MD; G5146LL; G5102DN; G5110DN; G5115DN; G5116MN; G5119LL; G5125DN;
G5126LL; G5150NK; G5147LL; G5141LL; G5147DN; G5102LL; G5106CL; G5110DX; G5115LL;
G5117DN; G5120DN; G5125AA; G5127DN; G5150NH; G5155DR; G5148DN; G5141MD;
G5156LL; G5256DN; G5107CL; G5111DN; G5114DN; G5117MN; G5120LL; G5124DN;
G5127LL; G5151DN; G5154DN; G5150LL; G5157DN; G5252LL; G5201DN; G52105LL;
G5208DN; G5211DX; G5214LL; G5218DN; G5221DN; G5224AA; G5228DN; G5251LL;
G5254NH; G5240DN; G5242DN; G5245LL; G5248LL; G5252DN; G5245DN; G5202LL;
G5206CL; G5210DX; G5215LL; G5217DN; G5220DN; G5225AA; G5227DN; G5250NH;
G5255DR; G5247LL; G5241MD; G5205DN; G5207CL; G5211DN; G5214DN; G5217MN;
G5220LL; G5224DN; G5227LL; G5251DN; G5254DN; G5248DN; G611DR; G621DR; G6122NK;
G6222NK; G311DN; G312AA; G311DX; G312NK; G311PH; G315DN; G315LL; G312DN;
G311CL; G312DX; G311NH; G312PH; G315SL; G315PH; G311LL; G312CL; G312NH; G315MD;
G315MN; G312LL; G311DR; G311DT; G316PH; G315DR; G311MD; G312DR; G311MN;
G312DT; G315NK; G315AA; G312MD; G311MQ; G312MN; G311SL; G315DX; G316AA;
G311AA; G312MQ; G311NK; G312SL; G315CL; G315MQ; G321AA; G322MQ; G321NK;
G322SL; G321DN; G322AA; G321DX; G322NK; G321PH; G325DN; G325LL; G322DN; G321CL;
G322DX; G321NH; G322PH; G325SL; G325PH; G321LL; G322CL; G321MP; G322NH;
G325MD; G325DR; G325MN; G322LL; G321DR; G322MP; G321DT; G326PH; G325AA;
G325MQ; G321MD; G322DR; G321MN; G322DT; G325NK; G326AA; G325CL; G322MD;
G321MQ; G322MN; G321SL; G325DX; G511DN; G512AA; G511DX; G512NK; G511PH;
G515DN; G515LL; G521DN; G522AA; G521DX; G522NK; G521PH; G525DN; G525LL; G512DN;
G511CL; G512DX; G511NH; G512PH; G515SL; G515PH; G522DN; G521CL; G522DX;
G521NH; G522PH; G525SL; G525PH; G511LL; G512CL; G511MP; G512NH; G515MD;
G515DR; G515MN; G521LL; G522CL; G521MP; G522NH; G525MD; G525DR; G525MN;
G512LL; G511DR; G512MP; G511DT; G516PH; G515AA; G515MQ; G522LL; G521DR;
G522MP; G521DT; G526PH; G525AA; G525MQ; G511MD; G512DR; G511MN; G512DT;
G515NK; G516AA; G515CL; G521MD; G522DR; G521MN; G522DT; G525NK; G526AA;
G525CL; G522SL; G521NK; G512MD; G511MQ; G512MN; G511SL; G515DX; G511AA;
G512MQ; G522MD; G521MQ; G522MN; G521SL; G525DX; G521AA; G522MQ; G111MQ;
G121MQ; K1101S; K1108S; K1115S; K1122S; K1201S; K1208S; K1215S; K1222S; K1102S;
K1109S; K1123S; K1202S; K1209S; K1218S; K1223S; K1103S; K1110S; K1117S; K1124S;
K1203S; K1210S; K1219S; K1224S; K1104S; K1111S; K1118S; K1125S; K1204S; K1211S;
K1221S; K1225S; K1105S; K1112S; K1119S; K1114S; K1205S; K1212S; K1207S; K1106S;
K1113S; K1107S; K1121S; K1206S; K1213S; K1214S; K1101P; K1108P; K1115P; K1122P;
K1201P; K1208P; K1215P; K1222P; K1102P; K1109P; K1118P; K1123P; K1202P; K1209P;
K1218P; K1223P; K1103P; K1110P; K1119P; K1124P; K1203P; K1210P; K1224P; K1104P;
K1111P; K1121P; K1125P; K1204P; K1211P; K1225P; K1105P; K1112P; K1205P; K1212P;

K1219P; K1207P; K1214P; K1106P; K1113P; K1206P; K1213P; K1221P; K1107P; K1114P; K1101N; K1108N; K1115N; K1122N; K1201N; K1208N; K1215N; K1222N; K1102N; K1109N; K1123N; K1202N; K1209N; K1223N; K1103N; K1110N; K1124N; K1203N; K1210N; K1224N; K1104N; K1111N; K1118N; K1125N; K1204N; K1211N; K1218N; K1225N; K1105N; K1112N; K1119N; K1205N; K1212N; K1219N; K1227N; K1106N; K1113N; K1206N; K1213N; K1107N; K1114N; K1121N; K1207N; K1214N; K1221N; K1101B; K1108B; K1115B; K1122B; K1201B; K1208B; K1215B; K1222B; K1102B; K1109B; K1123B; K1202B; K1209B; K1223B; K1103B; K1110B; K1124B; K1203B; K1210B; K1218B; K1224B; K1104B; K1111B; K1118B; K1125B; K1204B; K1211B; K1219B; K1225B; K1105B; K1112B; K1119B; K1127B; K1205B; K1212B; K1227B; K1106B; K1113B; K1206B; K1213B; K1221B; K1107B; K1114B; K1121B; K1207B; K1214B; K1106MQ; K1206MQ; K1106GE; K1206GE; K111MQ; K112MQ; K113MQ; K114MQ; K114PH; K121PH; K121MQ; K122MQ; K123MQ; K124MQ; K122PH; K123PH; K111GE; K112GE; K113GE; K114GE; K123TC; K124PH; K121GE; K122GE; K123GE; K124GE; K124TC; K111PH; K121MT; K122MT; K112PH; K112TC; K113TC; K114TC; K113PH

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

Período de vida útil: 5 (cinco) 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): Mantener en un lugar fresco y seco, alejado de la luz del sol, incluida la luz UV, tanto durante su almacenamiento como durante el transporte.

Nombre del fabricante: Shenzhen MedKe Technology Co., Ltd.

Lugar de elaboración: 401, 503, Bldg. A1, Anle Ind. Zone, No. 172, Hangcheng RD., Sanwei Community, Hangcheng Street, Baoan District, 518126 Shenzhen, People's Republic of 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 2362-26, siendo su vigencia hasta el 14 agosto 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° Identificadorio Trámite: 80633	
Tramitada por Expediente N°: 1-0047-3110-006193-26-0	