

第一类医疗器械备案信息表

备案编号：粤中械备 20180119 号

备案人名称	中山市康政医疗器材有限公司
备案人统一社会信用代码	914420000867945843
备案人住所	中山市小榄镇裕民社区同兴东路泽和街 3 号
生产地址	中山市小榄镇裕民社区同兴东路泽和街 3 号
代理人	/
代理人住所	/
产品名称	手拐杖
型号/规格	KL5103, KL5770, KL5611, KL5111, KL510, KA5102, KL5711, KL5619, KL5603, KL5612, KL5604, KL5312, KL5306, KL5307, KL5112, KL5115, KL5613, KA5503, KA5502, KL5501, KL5502, KL5509, KL5503, KL5504, KL5505, KL5506, KL5538, KL5407, KL5408, KL5520, KL5805, KL5804, KL5831, KL5813, KL5829, KL5830, KL5821, KL5820, KL5404, KCT004, KCT005, KCT006, KCT007, KCT008, KCT009, KCT010, KL5605, BYS2101, BYS2102, BYS2103, BYA2106, BYA2108, BYA2109, BYS2301, BYS2302, BYS2303, BYA2306, BYA2308, BYA2309, BYS2401, BYS2402, BYS2403, BYA2406, BYA2408, BYA2409, KF211, KF212, KF213, KF214, KF215, KF216, KF217, KF218, KF219, KF241, KF242, KF243, KF244, KF245, KF246, KF48, KF249, BYS2104, BYS2105, BYS2106, BYS2107, BYS2108, BYS2109, BYA2101, BYA2102, BYA2103, BYA2104, BYA2105, BYA2107, BYS2304, BYS2305, BYS2306, BYS2307, BYS2308, BYS2309, BYA2301, BYA2302, BYA2303, BYA2304, BYA2305, BYA2307, BYS2404, BYS2405, BYS2406, BYS2407, BYS2408, BYS2409, BYA2401, BYA2402, BYA2403, BYA2404, BYA2405, BYA2407, LGZ100, LGZ101, LGZ600, LGZ103, LGZ601, LGZ300, LGZ102, LGZ105, LGZ106, LGZ107, LGZ108, LGZ109, LGZ110, LGZ310, LGZ320, LGZ330, LGZ350, LGZ360, LGZ610, LGZ620, LGZ630, LGZ650, LGZ660, LGZ670
产品描述	由握把、脚垫和支撑管件组成。
预期用途	用于行动障碍患者的辅助行走或站立，进行康复训练。
备注	/
备案部门 备案日期	中山市市场监督管理局 备案日期：2018 年 07 月 13 日
变更情况	2024 年 11 月 06 日住所由“中山市东升镇兆益路 96 号；增设一处经营场所，具体为：中山市东升镇兆益路 61 号（一照多址）”变更为“中山市小榄镇裕民社区同兴东路泽和街 3 号”；生产地址由“中山市东升镇兆益路 96 号；中山市东升镇兆益路 61 号”变更为“中山市小榄镇裕民社区同兴东路泽和街 3 号”；型号规格由“KL5103, KL5770, KL5611, KL5111, KL510, KA5102, KL5711, KL5619, KL5603, KL5612, KL5604, KL5312, KL5306, KL5307, KL5112,

KL5115, KL5613, KA5503, KA5502, KL5501, KL5502, KL5509, KL5503, KL5504, KL5505, KL5506, KL5538, KL5407, KL5408, KL5520, KL5805, KL5804, KL5831, KL5813, KL5829, KL5830, KL5821, KL5820, KL5404, KCT004, KCT005, KCT006, KCT007, KCT008, KCT009, KCT010, KL5605, BYS2101, BYS2102, BYS2103, BYA2106, BYA2108, BYA2109, BYS2301, BYS2302, BYS2303, BYA2306, BYA2308, BYA2309, BYS2401, BYS2402, BYS2403, BYA2406, BYA2408, BYA2409, KF211, KF212, KF213, KF214, KF215, KF216, KF217, KF218, KF219, KF241, KF242, KF243, KF244, KF245, KF246, KF48, KF249, BYS2104, BYS2105, BYS2106, BYS2107, BYS2108, BYS2109, BYA2101, BYA2102, BYA2103, BYA2104, BYA2105, BYA2107, BYS2304, BYS2305, BYS2306, BYS2307, BYS2308, BYS2309, BYA2301, BYA2302, BYA2303, BYA2304, BYA2305, BYA2307, BYS2404, BYS2405, BYS2406, BYS2407, BYS2408, BYS2409, BYA2401, BYA2402, BYA2403, BYA2404, BYA2405, BYA2407” 变更为 “KL5103, KL5770, KL5611, KL5111, KL510, KA5102, KL5711, KL5619, KL5603, KL5612, KL5604, KL5312, KL5306, KL5307, KL5112, KL5115, KL5613, KA5503, KA5502, KL5501, KL5502, KL5509, KL5503, KL5504, KL5505, KL5506, KL5538, KL5407, KL5408, KL5520, KL5805, KL5804, KL5831, KL5813, KL5829, KL5830, KL5821, KL5820, KL5404, KCT004, KCT005, KCT006, KCT007, KCT008, KCT009, KCT010, KL5605, BYS2101, BYS2102, BYS2103, BYA2106, BYA2108, BYA2109, BYS2301, BYS2302, BYS2303, BYA2306, BYA2308, BYA2309, BYS2401, BYS2402, BYS2403, BYA2406, BYA2408, BYA2409, KF211, KF212, KF213, KF214, KF215, KF216, KF217, KF218, KF219, KF241, KF242, KF243, KF244, KF245, KF246, KF48, KF249, BYS2104, BYS2105, BYS2106, BYS2107, BYS2108, BYS2109, BYA2101, BYA2102, BYA2103, BYA2104, BYA2105, BYA2107, BYS2304, BYS2305, BYS2306, BYS2307, BYS2308, BYS2309, BYA2301, BYA2302, BYA2303, BYA2304, BYA2305, BYA2307, BYS2404, BYS2405, BYS2406, BYS2407, BYS2408, BYS2409, BYA2401, BYA2402, BYA2403, BYA2404, BYA2405, BYA2407, LGZ100, LGZ101, LGZ600, LGZ103, LGZ601, LGZ300, LGZ102, LGZ105, LGZ106, LGZ107, LGZ108, LGZ109, LGZ110, LGZ310, LGZ320, LGZ330, LGZ350, LGZ360, LGZ610, LGZ620, LGZ630, LGZ650, LGZ660, LGZ670”。

境内备案人委托生产的：备注栏应当标注受托企业名称。

备案人应当确保提交的资料合法、真实、准确、完整和可追溯。

备案人实际生产产品应当与备案信息一致。



第一类医疗器械备案信息表

备案编号：粤中械备 20180120 号

备案人名称	中山市康政医疗器材有限公司
备案人统一社会信用代码	914420000867945843
备案人住所	中山市小榄镇裕民社区同兴东路泽和街 3 号
生产地址	中山市小榄镇裕民社区同兴东路泽和街 3 号
代理人	/
代理人住所	/
产品名称	腋下拐
型号/规格	KL570, KL5708, KL5709, KL5710, KL5701, KL5702, KL5703, KL5704, KL5754, KL5797, KA5788, KCA001, KCA002, KCA003, KCA004, KCG001, KCG002, KCG003, KCG004, KCT001, KCT002, KCT003, BYS2201, BYS2202, BYS2202Z, BYS2206, BYS2208, BYS2209, BYA2201, BYA2202, BYA2203, BYA2206, BYA2208, BYA2209, BYS2201Z, BYS2203Z, KF221, KF222, KF223, KF224, KF225, KF226, KF227, KF228, KF229, BYS2203, BYS2204, BYS2205, BYS2207, BYS2210, BYS2211, BYS2212, BYS2213, BYS2214, BYS2215, BYS2216, BYS2217, BYS2218, BYS2219, BYS2220, BYA2204, BYA2205, BYA2207, BYA2210, BGZ201, BGZ202, BGZ203, BGZ201D, BGZ202D, BGZ203D, LGZ201, LGZ202, LGZ203, LGZ201D, LGZ202D, LGZ203D, BGZ210, BGZ220, BGZ230, BGZ240, BGZ250, BGZ260, LGZ210, LGZ220, LGZ230, LGZ240, LGZ250, LGZ260
产品描述	由扶肩、握把、脚垫和支撑管件组成，无源产品。
预期用途	用于行动障碍患者的辅助行走或站立，进行康复训练。
备注	/
备案部门 备案日期	中山市市场监督管理局 备案日期：2018 年 07 月 13 日
变更情况	2024 年 11 月 06 日住所由“中山市东升镇兆益路 96 号”增设一处经营场所，具体为：中山市东升镇兆益路 61 号（一照多址）”变更为“中山市小榄镇裕民社区同兴东路泽和街 3 号”；生产地址由“中山市东升镇兆益路 96 号；中山市东升镇兆益路 61 号”变更为“中山市小榄镇裕民社区同兴东路泽和街 3 号”；型号规格由“KL570, KL5708, KL5709, KL5710, KL5701, KL5702, KL5703, KL5704, KL5754, KL5797, KA5788, KCA001, KCA002, KCA003, KCA004, KCG001, KCG002, KCG003, KCG004, KCT001, KCT002, KCT003, BYS2201, BYS2202, BYS2202Z, BYS2206, BYS2208, BYS2209, BYA2201, BYA2202, BYA2203, BYA2206, BYA2208, BYA2209, BYS2201Z, BYS2203Z, KF221, KF222, KF223, KF224, KF225, KF226, KF227, KF228, KF229, BYS2203, BYS2204, BYS2205, BYS2207, BYS2210, BYS2211, BYS2212, BYS2213, BYS2214, BYS2215, BYS22

	16,BYS2217,BYS2218,BYS2219,BYS2220,BYA2204,BYA2205,BYA2207,BYA2210” 变更为 “KL570,KL5708,KL5709,KL5710,KL5701,KL5702,KL5703,KL5704,KL5754,KL5797,KA5788,KCA001,KCA002,KCA003,KCA004,KCG001,KCG002,KCG003,KCG004,KCT001,KCT002,KCT003,BYS2201,BYS2202,BYS2202Z,BYS2206,BYS2208,BYS2209,BYA2201,BYA2202,BYA2203,BYA2206,BYA2208,BYA2209,BYS2201Z,BYS2203Z,KF221,KF222,KF223,KF224,KF225,KF226,KF227,KF228,KF229,BYS2203,BYS2204,BYS2205,BYS2207,BYS2210,BYS2211,BYS2212,BYS2213,BYS2214,BYS2215,BYS2216,BYS2217,BYS2218,BYS2219,BYS2220,BYA2204,BYA2205,BYA2207,BYA2210,BGZ201,BGZ202,BGZ203,BGZ201D,BGZ202D,BGZ203D,LGZ201,LGZ202,LGZ203,LGZ201D,LGZ202D,LGZ203D,BGZ210,BGZ220,BGZ230,BGZ240,BGZ250,BGZ260,LGZ210,LGZ220,LGZ230,LGZ240,LGZ250,LGZ260” 。
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境内备案人委托生产的；备注栏应当标注受托企业名称。

备案人应当确保提交的资料合法、真实、准确、完整和可追溯。

备案人实际生产产品应当与备案信息一致。



第一类医疗器械备案信息表

备案编号：粤中械备 20180121 号

备案人名称	中山市康政医疗器材有限公司
备案人统一社会信用代码	914420000867945843
备案人住所	中山市小榄镇裕民社区同兴东路泽和街 3 号
生产地址	中山市小榄镇裕民社区同兴东路泽和街 3 号
代理人	/
代理人住所	/
产品名称	助行器
型号/规格	KL2109,KL2120,KL2218,KA2169,KA2102,KL2108,KL2143,KL2142,KL2145,KL2104,KA2242,KA2201,KL2228,KL2210,KL2205,KL2220,KA2243,KL2229,KL2307,KL2304,KL2306,KL2243,KL2248,KA2265,KA2266,KA2263,KA2264,KL2501,KL2502,KL2158,KL2504,KA2205,KL2110,KS3107,KL9101,KWT001,KWT002,KWT003,KWT004,KWT005,KWT006,KWT007,KWT008,KWT009,KWT010,KWT011,KWT012,KWT013,KWT014,KWG001,KWG002,KWG003,KWG004,KWG005,KWG006,KWG007,KWTC001,KL9304,KL9301,KL9305,RSG001,RSG002,RSG003,KL9306,KL9310,KA9307,KL9309,KL9308,KA9311,KA9312,KL9310,KA2162,KA2163,KA2164,KA2165,KL2102,KL2154,BYS3101,BYS3102,BYS3103,BYA3106,BYA3108,BYA3109,BYS3201,BYS3202,BYS3203,BYA3206,BYA3208,BYA3209,BYS3301,BYS3302,BYS3303,BYA3306,BYA3308,BYA3309,BYS301,BYS302,BYS303,BYS304,BYS305,BYS306,BYS307,BYS308,BYS309,BYA301,BYA302,BYA303,BYA304,BYA305,BYA306,BYA307,BYA308,BYA309,BYS510,BYS520,BYS530,BYS540,BYS550,BYS560,BYS570,BYS580,BYS590,BYS501,BYS502,BYS503,BYS504,BYS505,BYS506,BYS507,BYS508,BYS509,BYP501,BYP502,BYP503,BYP504,BYP505,BYP506,BYP507,BYP508,BYP509,KF331,KF332,KF333,KF334,KF335,KF336,KF337,KF338,KF339,BYS3104,BYS3105,BYA3105,BYA3107,BYS3204,BYS3205,BYA3205,BYA3207,BYS3304,BYS3305,BYA3305,BYA3307,ATC600,ATC602S,LZX300,LZX200,ATC600S,ATC601S,ATC700,LTC710,ATC800,LTC810,ATC900,LTC910,LXB600,LXB610,LXB620,LXB630,LXB650,LXB660,LXB670,LXB680,LXB690,LXB700,LXB710,LXB720,LXB730,LXB750,LXB760,LXB770,LXB780,LXB790
产品描述	由铝管主架、铁管连接管、橡胶握把和橡胶脚垫组成。
预期用途	用于行动障碍患者的辅助行走或站立，进行康复训练
备注	/
备案部门 备案日期	中山市市场监督管理局 备案日期：2018 年 07 月 13 日
变更情况	2024 年 11 月 06 日住所由“中山市东升镇兆益路 96 号”增设一处经营场所，具体为：中山市东升镇兆益路 61 号（一照多址）”变更为“中山市小榄镇

裕民社区同兴东路泽和街3号”；生产地址由“中山市东升镇兆益路96号；中山市东升镇兆益路61号”变更为“中山市小榄镇裕民社区同兴东路泽和街3号”；型号规格由“KL2109, KL2120, KL2218, KA2169, KA2102, KL2108, KL2143, KL2142, KL2145, KL2104, KA2242, KA2201, KL2228, KL2210, KL2205, KL2220, KA2243, KL2229, KL2307, KL2304, KL2306, KL2243, KL2248, KA2265, KA2266, KA2263, KA2264, KL2501, KL2502, KL2158, KL2504, KA2205, KL2110, KS3107, KL9101, KWT001, KWT002, KWT003, KWT004, KWT005, KWT006, KWT007, KWT008, KWT009, KWT010, KWT011, KWT012, KWT013, KWT014, KWG001, KWG002, KWG003, KWG004, KWG005, KWG006, KWG007, KWTC001, KL9304, KL9301, KL9305, RSG001, RSG002, RSG003, KL9306, KL9310, KA9307, KL9309, KL9308, KA9311, KA9312, KL9310, KA2162, KA2163, KA2164, KA2165, KL2102, KL2154, BYS3101, BYS3102, BYS3103, BYA3106, BYA3108, BYA3109, BYS3201, BYS3202, BYS3203, BYA3206, BYA3208, BYA3209, BYS3301, BYS3302, BYS3303, BYA3306, BYA3308, BYA3309, BYS301, BYS302, BYS303, BYS304, BYS305, BYS306, BYS307, BYS308, BYS309, BYA301, BYA302, BYA303, BYA304, BYA305, BYA306, BYA307, BYA308, BYA309, BYS510, BYS520, BYS530, BYS540, BYS550, BYS560, BYS570, BYS580, BYS590, BYS501, BYS502, BYS503, BYS504, BYS505, BYS506, BYS507, BYS508, BYS509, BYP501, BYP502, BYP503, BYP504, BYP505, BYP506, BYP507, BYP508, BYP509, KF331, KF332, KF333, KF334, KF335, KF336, KF337, KF338, KF339, BYS3104, BYS3105, BYA3105, BYA3107, BYS3204, BYS3205, BYA3205, BYA3207, BYS3304, BYS3305, BYA3305, BYA3307”变更为“KL2109, KL2120, KL2218, KA2169, KA2102, KL2108, KL2143, KL2142, KL2145, KL2104, KA2242, KA2201, KL2228, KL2210, KL2205, KL2220, KA2243, KL2229, KL2307, KL2304, KL2306, KL2243, KL2248, KA2265, KA2266, KA2263, KA2264, KL2501, KL2502, KL2158, KL2504, KA2205, KL2110, KS3107, KL9101, KWT001, KWT002, KWT003, KWT004, KWT005, KWT006, KWT007, KWT008, KWT009, KWT010, KWT011, KWT012, KWT013, KWT014, KWG001, KWG002, KWG003, KWG004, KWG005, KWG006, KWG007, KWTC001, KL9304, KL9301, KL9305, RSG001, RSG002, RSG003, KL9306, KL9310, KA9307, KL9309, KL9308, KA9311, KA9312, KL9310, KA2162, KA2163, KA2164, KA2165, KL2102, KL2154, BYS3101, BYS3102, BYS3103, BYA3106, BYA3108, BYA3109, BYS3201, BYS3202, BYS3203, BYA3206, BYA3208, BYA3209, BYS3301, BYS3302, BYS3303, BYA3306, BYA3308, BYA3309, BYS301, BYS302, BYS303, BYS304, BYS305, BYS306, BYS307, BYS308, BYS309, BYA301, BYA302, BYA303, BYA304, BYA305, BYA306, BYA307, BYA308, BYA309, BYS510, BYS520, BYS530, BYS540, BYS550, BYS560, BYS570, BYS580, BYS590, BYS501, BYS502, BYS503, BYS504, BYS505, BYS506, BYS507, BYS508, BYS509, BYP501, BYP502, BYP503, BYP504, BYP505, BYP506, BYP507, BYP508, BYP509, KF331, KF332, KF333, KF334, KF335, KF336, KF337, KF338, KF339, BYS3104, BYS3105, BYA3105, BYA3107, BYS3204, BYS3205, BYA3205, BYA3207, BYS3304, BYS3305, BYA3305, BYA3307, ATC600, ATC602S, LZX300, LZX200, ATC600S, ATC601S, ATC700, LTC710, ATC800, LTC810, ATC900, LTC910, LXB600, LXB610, LXB620, LXB630, LXB650, LXB660, LXB670, LXB680, LXB690, LXB700, LXB710, LXB720, LXB730, LXB750, LXB760, LXB770, LXB780, LXB790”。

境内备案人委托生产的；备注栏应当标注受托企业名称。



备案人应当确保提交的资料合法、真实、准确、完整和可追溯。
备案人实际生产产品应当与备案信息一致。

