

第一类医疗器械备案信息表

备案编号：粤中械备 20240002

备案人名称	广东晋大康复护理用品有限公司
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代理人	/
代理人住所	/
产品名称	医用拐
型号/规格	LM4901TA、LM4901TB、LM4901TC、LM4902JA、LM4902JB、LM4902JC、LM4902HA、LM4902HB、LM4902HC、LM4902TA、LM4902TB、LM4902TC、LM4903TA、LM4903TB、LM4903TC、LM4903TAF、LM4903TBF、LM4903TCF、LM4904TA、LM4904TB、LM4904TC、LM4904TAF、LM4904TBF、LM4904TCF、LM4905TA、LM4905TB、LM4905TC、LM4905TAF、LM4905TBF、LM4905TCF、LM4906TA、LM4906TB、LM4906TC、LM4906TAF、LM4906TBF、LM4906TCF、LM4800LA、LM4800LB、LM4800LC、LM4800LAF、LM4800LBF、LM4800LCF、LM4801LA、LM4801LB、LM4801LC、LM4801LAF、LM4801LBF、LM4801LCF、LM4802LA、LM4802LB、LM4802LC、LM4802LAF、LM4802LBF、LM4802LCF、LM4803LA、LM4803LB、LM4803LC、LM4803LAF、LM4803LBF、LM4803LCF、LM4804LA、LM4804LB、LM4804LC、LM4804LAF、LM4804LBF、LM4804LCF、LM4805LA、LM4805LB、LM4805LC、LM4805LAF、LM4805LBF、LM4805LCF、LM4900、KJ4901TA、KJ4901TB、KJ4901TC、KJ4902JA、KJ4902JB、KJ4902JC、KJ4902HA、KJ4902HB、KJ4902HC、KJ4902TA、KJ4902TB、KJ4902TC、KJ4903TA、KJ4903TB、KJ4903TC、KJ4903TAF、KJ4903TBF、KJ4903TCF、KJ4904TA、KJ4904TB、KJ4904TC、KJ4904TAF、KJ4904TBF、KJ4904TCF、KJ4905TA、KJ4905TB、KJ4905TC、KJ4905TAF、KJ4905TBF、KJ4905TCF、KJ4906TA、KJ4906TB、KJ4906TC、KJ4906TAF、KJ4906TBF、KJ4906TCF、KJ4900、LM4201S2、LM4201M2、LM4201L2、LM4301M2、LM4301L2、LM4203S2、LM4203M2、LM4203L2、LM4204S2、LM4204M2、LM4204L2、LM4205S2、LM4205M2、LM4205L2、LM4206S2、LM4206M2、LM4206L2、LM4207S2、LM4207M2、LM4207L2、LM4208S2、LM4208M2、LM4207L2、KJ4201S2、LM4201M2、LM4201L2、KJ4301M2、LM4301L2、KJ4203S2、KJ4203M2、KJ4203L2、KJ4204S2、KJ4204M2、KJ4204L2、KJ4205S2、KJ4205M2、KJ4205L2、KJ4206S2、KJ4206M2、KJ4206L2、KJ4207S2、KJ4207M2、KJ4207L2、KJ4208S2、KJ4208M2、KJ4207L2、LM4200S1、LM4200S2、LM4200M1、LM4200M2、LM4200L1、LM4200L2、LM4400S1、LM4400S2、LM4400M1、LM4400M2、LM4400L1、LM4400L2。
产品描述	由支脚、手柄、支撑托、支撑架组成。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 行政审批专用章 备案日期：2024年01月11日
变更情况	2025年2月28日，型号/规格由“LM4901TA、LM4901TB、LM4901TC、LM4902JA、LM4902JB、LM4902JC、LM4902HA、LM4902HB、LM4902HC、LM4902TA、LM4902TB、LM4902TC、KJ4901TA、KJ4901TB、KJ4901TC、KJ4902JA、KJ4902JB、KJ4902JC、KJ4902HA、KJ4902HB、KJ4902HC、KJ4902TA、KJ4902TB、KJ4902TC、LM4200S1、LM4200S2、LM4200M1、LM4200M2、LM4200L1、LM4200L2、LM4400S1、LM4400S2、LM4400M1、LM4400M2、LM4400L1、LM4400L2。”变更为“LM4901TA、LM4901TB、LM4901TC、LM4902JA、LM4902JB、LM4902JC、LM4902HA、LM4902HB、LM4902HC、LM4902TA、LM4902TB、LM4902TC、LM4903TA、LM4903TB、LM4903TC、LM4903TAF、LM4903TBF、LM4903TCF、LM4904TA、LM4904TB、LM4904TC、LM4904TAF、LM4904TBF、LM4904TCF、LM4905TA、LM4905TB、LM4905TC、LM4905TAF、LM4905TBF、LM4905TCF、LM4906TA、LM4906TB、LM4906TC、LM4906TAF、LM4906TBF、LM4906TCF、LM4800LA、LM4800LB、LM4800LC、LM4800LAF、LM4800LBF、LM4800LCF、LM4801LA、LM4801LB、LM4801LC、LM4801LAF、LM4801LBF、LM4801LCF、LM4802LA、LM4802LB、LM4802LC、LM4802LAF、LM4802LBF、LM4802LCF、LM4803LA、LM4803LB、LM4803LC、LM4803LAF、LM4803LBF、LM4803LCF、LM4804LA、LM4804LB、LM4804LC、LM4804LAF、LM4804LBF、LM4804LCF、LM4805LA、LM4805LB、LM4805LC、LM4805LAF、LM4805LBF、LM4805LCF、LM4900、KJ4901TA、KJ4901TB、KJ4901TC、KJ4902JA、KJ4902JB、KJ4902JC、KJ4902HA、KJ4902HB、KJ4902HC、KJ4902TA、KJ4902TB、KJ4902TC、KJ4903TA、KJ4903TB、KJ4903TC、KJ4903TAF、KJ4903TBF、KJ4903TCF、KJ4904TA、KJ4904TB、KJ4904TC、KJ4904TAF、KJ4904TBF、KJ4904TCF、KJ4905TA、KJ4905TB、KJ4905TC、KJ4905TAF、KJ4905TBF、KJ4905TCF、KJ4906TA、KJ4906TB、KJ4906TC、KJ4906TAF、KJ4906TBF、KJ4906TCF、KJ4900、LM4201S2、LM4201M2、LM4201L2、LM4301M2、LM4301L2、LM4203S2、LM4203M2、LM4203L2、LM4204S2、LM4204M2、LM4204L2、LM4205S2、LM4205M2、LM4205L2、LM4206S2、LM4206M2、LM4206L2、LM4207S2、LM4207M2、LM4207L2、LM4208S2、LM4208M2、LM4207L2、KJ4201S2、LM4201M2、LM4201L2、KJ4301M2、LM4301L2、KJ4203S2、KJ4203M2、KJ4203L2、KJ4204S2、KJ4204M2、KJ4204L2、KJ4205S2、KJ4205M2、KJ4205L2、KJ4206S2、KJ4206M2、KJ4206L2、KJ4207S2、KJ4207M2、KJ4207L2、KJ4208S2、KJ4208M2、KJ4207L2、LM4200S1、LM4200S2、LM4200M1、LM4200M2、LM4200L1、LM4200L2、LM4400S1、LM4400S2、LM4400M1、LM4400M2、LM4400L1、LM4400L2。”；变更产品技术要求。

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。