

第一类医疗器械备案信息表

备案号：闽莆械备 20140001 号

备案人名称	福建亿发卫生用品有限公司
备案人统一社会信用代码	913503005831287185
备案人住所	莆田市涵江区新涵工业区
生产地址	福建省莆田市涵江区新涵工业区
代理人	——
代理人住所	——
产品名称	护理垫（基本型）、护理垫（腰打型）
型号/规格	SW01-150-30, SW01-195-16, SW01-245-10, SW01-285-8, SW01-350-8, SW01-420-6, SW02-245-10, SW02-285-8, SW02-350-8, LCP01-420-12, LCN01-3L/XL, LCN01-3M/L, LCP02-420, LCP03-420, LCN02-L, SCD02-6L, SCD02-15L, SCD02-20M, SCD02-8M, SCD03-10L, SCD05-S, SCD05-M, SCD05-L, DCD01-20M, DCD01-20L, DCD02-5L, SCK03-10M/L, SCK03-10L/XL, SCK07-M, SCK07-L, SCK07-XL, SCK07-XXL, KCK05-10M/L, KCK05-10L/XL, SCN01-20L, SCN01-18XL, SCN02-5L, KCP05-16L/XL, KCP05-36L, SCN08-M, SCN08-L, SCN08-XL, SCP08-M, SCP08-L, SCP08-XL, SK19-28NB, SK19-76NB, SK19-70S, SK19-60M, SK19-52L, SK19-44XL, SK19-40XXL, SK19-38XXXL, NK19-42L, NK19-40XL, NK19-38XXL, NK19-36XXXL, NK19-34XXXL, SK20-NB, SK21-NB, SK21-S, SK21-M, SK21-L, SK21-XL, SK21-XXL, NK21-M, NK21-L, NK21-XL, NK21-XXL, NK21-XXXL, SK22-12NB, SK21, NK21, SW04-240, SW04-290, SW04-330, SCD03-2L, JC-240-10, JC-290-8, JC-155-20.
产品描述	通常由非织造布和 PE 膜复合或缝制而成。非无菌提供，一次性使用。主要成份：无纺布、吸水纸、绒毛浆、高分子吸收树脂、PE 膜等。
预期用途	病床或检查床上用的卫生护理用品。
备注	——
备案部门	莆田市市场监督管理局
备案日期	备案日期：2025 年 06 月 03 日
变更情况	2025 年 06 月 03 日变更型号/规格及产品技术要求，型号/规格由“SCK03-10M/L; SCK03-10L/XL; SCD02-6L; SCD02-15L; SCD02-20M; SCD03-10L; SW01-150-30; SW01-195-16; SW01-245-10; SW01-285-8; SW01-350-8; SW02-245-10; SW02-285-8; SW02-350-8; SCN01-20L; SCN01-18XL; SCN02-5L; SK19-76NB; SK19-70S; SK19-60M; SK19-52L; SK19-44XL; SK19-40XXL; NK19-42L; NK19-40XL; NK19-38XXL; NK19-36XXXL; KCK05-10M/L; KCK05-10L/XL; KCD05-10L; KCD05-15L; KCP05-16L/XL; KCP05-36L; DCD02-5L; SCD02-2XL; SK18-82NB; SK18-76S; SK18-62M; SK18-54L; SK18-48XL; XSC01-10S; XSC01-10M; XSC01-10L; XSC01-10XL; LCN01-3M/L; LCN01-3L/XL; SW01-420-6; LCP01-420-12; SCD02-8M; DCD01-20M; DCD01-20L; ZK02-NB; ZK02-S; ZK02-M; ZK02-L; ZK02-XL; ZK02-XXL; ZZN02-L; ZZN02-XL; ZZN02-XXL; ZZN02-XXXL; SCD05-S; SCD05-M; SCD05-L; LCP02-420; LCP03-420; LCN02-M; LCN02-L; LCN03-M; LCN03-L; SK20-NB; SK20-S; SK20-M; SK20-L; SK20-XL; SK20-XXL; SK20-XXXL; SK21-NB; SK21-S; SK21-M; SK21-L; SK21-XL; SK21-XXL; NK20-M; NK20-L; NK20-XL; NK20-XXL; NK20-XXXL; NK20-XXXXL; NK21-M; NK21-L; NK21-XL; NK21-XXL; NK21-XXXL; SCK07-M; SCK07-L; SCK07-XL; SCK07-XXL; SCK08-M; SCK08-L; SCK08-XL; SCK08-XXL; SCN07-M; SCN07-L; SCN07-XL; SCN08-M; SCN08-L; SCN08-XL; SCP08-M; SCP08-L; SCP08-XL; SCD07-S; SCD07-M; SCD07-L; SCD08-S; SCD08-M; SCD08-L; SCD09-S; SCD09-M; SCD09-L; SCK09-M; SCK09-L; SCK09-XL; SCK09-XXL; SK19-28NB; SK19-38XXXL; NK19-34XXXL; SK22-12NB; SK21; NK21; SW04-240-10; SW04-290-8; SW04-330-6; SCD03-2L; JC-240-10; JC-290-8.”变更为“SW01-150-30, SW01-195-16, SW01-245-10, SW01-285-8, SW01-350-8, SW01-420-6, SW02-245-10, SW02-285-8, SW02-350-8, LCP01-420-12, LCN01-3L/XL, LCN01-3M/L, LCP02-420, LCP03-420, LCN02-L, SCD02-6L, SCD02-15L, SCD02-20M, SCD02-8M, SCD03-10L, SCD05-S, SCD05-M, SCD05-L, DCD01-20M, DCD01-20L, DCD02-5L, SCK03-10M/L, SCK03-10L/XL, SCK07-M, SCK07-L, SCK07-XL, SCK07-XXL, KCK05-10M/L, KCK05-10L/XL, SCN01-20L, SCN01-18XL, SCN02-5L, KCP05-16L/XL, KCP05-36L, SCN08-M, SCN08-L, SCN08-XL, SCP08-M, SCP08-L, SCP08-XL, SK19-28NB, SK19-76NB, SK19-70S, SK19-60M, SK19-52L, SK19-44XL, SK19-40XXL, SK19-38XXXL, NK19-42L, NK19-40XL, NK19-38XXL, NK19-36XXXL, NK19-34XXXL, SK20-NB, SK21-NB, SK21-S, SK21-L, SK21-XL, SK21-XXL, NK21-M, NK21-L, NK21-XL, NK21-XXL, NK21-XXXL, SK22-12NB, SK21, NK21, SW04-240, SW04-290, SW04-330, SCD03-2L, JC-240-10, JC-290-8, JC-155-20.”

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。