

# 第一类医疗器械备案信息表

备案号：闽莆械备 20140001 号

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| 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（腰扣型）                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| 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, SW06-155-20, SW06-240-10, SW06-290-8, SW06-330-6, LCN03-3L。                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| 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 20 日                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| 变更情况        | 2025 年 06 月 20 日变更型号/规格及产品技术要求，型号/规格由“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。”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-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, SW06-155-20, SW06-240-10, SW06-290-8, SW06-330-6, LCN03-3L。” |

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。