

THÔNG TIN

Hồ sơ công bố tiêu chuẩn áp dụng của trang thiết bị y tế thuộc loại B

Số công bố: 220001994/PCBB-HN

Ngày công bố: 10/06/2022

1. Tên cơ sở công bố: CÔNG TY TNHH THƯƠNG MẠI Y TẾ VÀ GIÁO DỤC LÊ VŨ
2. Địa chỉ: Số 2/117 đường Trần Cung, tập thể Bộ Tư Lệnh Thông Tin, tổ dân phố Hoàng 3, Phường Cổ Nhuế 1, Quận Bắc Từ Liêm, Thành phố Hà Nội
3. Số văn bản của cơ sở: 2005_Inject/LV-2022 Ngày: 02/06/2022
4. Trang thiết bị y tế thuộc loại B
Tên trang thiết bị y tế: Kim tiêm cầm máu dùng một lần
Tên thương mại:
Mã Global Medical Device Nomenclature – GMDN (nếu có):
Chủng loại: Theo phụ lục
Mã sản phẩm (nếu có): Theo phụ lục
Quy cách đóng gói: 1 Cái/ túi
Mục đích sử dụng: Cầm máu trong nội soi tiêu hóa sử dụng kèm với hệ thống nội soi tiêu hóa chẩn đoán
Tên cơ sở sản xuất: Theo phụ lục
Địa chỉ cơ sở sản xuất: Theo phụ lục
Tiêu chuẩn chất lượng sản phẩm áp dụng: ISO 13485: 2016
5. Đối với trang thiết bị y tế chứa chất ma túy, tiền chất (nếu có):
6. Thông tin về chủ sở hữu trang thiết bị y tế:
Tên chủ sở hữu: JIANGSU ATE MEDICAL TECHNOLOGY CO.,LTD
Địa chỉ chủ sở hữu: No. 8, Lanxiang Road, Wujin Economic Development Zone, 213161 Jiangsu, Trung Quốc
7. Thông tin về cơ sở bảo hành (nếu có):
8. Số công bố đủ điều kiện sản xuất đối với trang thiết bị y tế sản xuất trong nước:

9. Thành phần hồ sơ:

1	Văn bản công bố tiêu chuẩn áp dụng đối với trang thiết bị y tế thuộc loại B	x
2	Giấy chứng nhận đạt tiêu chuẩn quản lý chất lượng ISO 13485	x
3	Giấy ủy quyền của chủ sở hữu trang thiết bị y tế	x
4	Giấy xác nhận đủ điều kiện bảo hành	x
5	Tài liệu mô tả tóm tắt kỹ thuật trang thiết bị y tế bằng tiếng Việt	x
6	Bản tiêu chuẩn mà chủ sở hữu trang thiết bị y tế công bố áp dụng	x
7	Giấy chứng nhận hợp chuẩn	x
8	Giấy chứng nhận lưu hành tự do đối với trang thiết bị y tế nhập khẩu	x

PHỤ LỤC: BẢNG KÊ CHI TIẾT TRANG THIẾT BỊ Y TẾ

STT	TÊN TRANG THIẾT BỊ Y TẾ	CHUNG LOẠI	MÃ SẢN PHẨM (Nếu có)	QUY CÁCH ĐÓNG GÓI (Nếu có)	TÊN CƠ SỞ SẢN XUẤT	ĐỊA CHỈ CƠ SỞ SẢN XUẤT	NƯỚC SẢN XUẤT
1	Kim tiêm cầm máu dùng một lần	ATE-ZSZ-18x1200x21x4 ATE-ZSZ-18x1200x21x5 ATE-ZSZ-18x1200x21x6 ATE-ZSZ-18x1200x21x7 ATE-ZSZ-18x1200x21x8 ATE-ZSZ-18x1200x23x4 ATE-ZSZ-18x1200x23x5 ATE-ZSZ-18x1200x23x6 ATE-ZSZ-18x1200x23x7 ATE-ZSZ-18x1200x23x8 ATE-ZSZ-18x1200x25x4 ATE-ZSZ-18x1200x25x5 ATE-ZSZ-18x1200x25x6 ATE-ZSZ-18x1200x25x7 ATE-ZSZ-18x1200x25x8 ATE-ZSZ-18x1600x21x4 ATE-ZSZ-18x1600x21x5 ATE-ZSZ-18x1600x21x6 ATE-ZSZ-18x1600x21x7 ATE-ZSZ-18x1600x21x8 ATE-ZSZ-18x1600x23x4 ATE-ZSZ-18x1600x23x5 ATE-ZSZ-18x1600x23x6 ATE-ZSZ-18x1600x23x7 ATE-ZSZ-18x1600x23x8 ATE-ZSZ-18x1600x25x4 ATE-ZSZ-18x1600x25x5 ATE-ZSZ-18x1600x25x6 ATE-ZSZ-18x1600x25x7 ATE-ZSZ-18x1600x25x8 ATE-ZSZ-18x1800x21x4 ATE-ZSZ-18x1800x21x5 ATE-ZSZ-18x1800x21x6 ATE-ZSZ-18x1800x21x7 ATE-ZSZ-18x1800x21x8 ATE-ZSZ-18x1800x23x4 ATE-ZSZ-18x1800x23x5 ATE-ZSZ-18x1800x23x6 ATE-ZSZ-18x1800x23x7 ATE-ZSZ-18x1800x23x8 ATE-ZSZ-18x1800x25x4 ATE-ZSZ-18x1800x25x5 ATE-ZSZ-18x1800x25x6 ATE-ZSZ-18x1800x25x7 ATE-ZSZ-18x1800x25x8 ATE-ZSZ-18x2000x21x4 ATE-ZSZ-18x2000x21x5 ATE-ZSZ-	ATE-ZSZ-18x1200x21x4 ATE-ZSZ-18x1200x21x5 ATE-ZSZ-18x1200x21x6 ATE-ZSZ-18x1200x21x7 ATE-ZSZ-18x1200x21x8 ATE-ZSZ-18x1200x23x4 ATE-ZSZ-18x1200x23x5 ATE-ZSZ-18x1200x23x6 ATE-ZSZ-18x1200x23x7 ATE-ZSZ-18x1200x23x8 ATE-ZSZ-18x1200x25x4 ATE-ZSZ-18x1200x25x5 ATE-ZSZ-18x1200x25x6 ATE-ZSZ-18x1200x25x7 ATE-ZSZ-18x1200x25x8 ATE-ZSZ-18x1600x21x4 ATE-ZSZ-18x1600x21x5 ATE-ZSZ-18x1600x21x6 ATE-ZSZ-18x1600x21x7 ATE-ZSZ-18x1600x21x8 ATE-ZSZ-18x1600x23x4 ATE-ZSZ-18x1600x23x5 ATE-ZSZ-18x1600x23x6 ATE-ZSZ-18x1600x23x7 ATE-ZSZ-18x1600x23x8 ATE-ZSZ-18x1600x25x4 ATE-ZSZ-18x1600x25x5 ATE-ZSZ-18x1600x25x6 ATE-ZSZ-18x1600x25x7 ATE-ZSZ-18x1600x25x8 ATE-ZSZ-18x1600x21x4 ATE-ZSZ-18x1600x21x5 ATE-ZSZ-18x1600x21x6 ATE-ZSZ-18x1600x21x7 ATE-ZSZ-18x1600x21x8 ATE-ZSZ-18x1600x23x4 ATE-ZSZ-18x1600x23x5 ATE-ZSZ-18x1600x23x6 ATE-ZSZ-18x1600x23x7 ATE-ZSZ-18x1600x23x8 ATE-ZSZ-18x1600x25x4 ATE-ZSZ-18x1600x25x5 ATE-ZSZ-18x1600x25x6 ATE-ZSZ-18x1600x25x7 ATE-ZSZ-18x1600x25x8 ATE-ZSZ-18x1600x21x4 ATE-ZSZ-18x1600x21x5 ATE-ZSZ-18x1600x21x6 ATE-ZSZ-18x1600x21x7 ATE-ZSZ-18x1600x21x8 ATE-ZSZ-18x1600x23x4 ATE-ZSZ-18x1600x23x5 ATE-ZSZ-18x1600x23x6 ATE-ZSZ-18x1600x23x7 ATE-ZSZ-18x1600x23x8 ATE-ZSZ-18x1600x25x4 ATE-ZSZ-18x1600x25x5 ATE-ZSZ-18x1600x25x6 ATE-ZSZ-18x1600x25x7 ATE-ZSZ-18x1600x25x8 ATE-ZSZ-18x1600x23x4 ATE-ZSZ-18x1600x23x5 ATE-ZSZ-18x1600x23x6 ATE-ZSZ-		JIANGSU ATE MEDICAL TECHNOLOGY CO.,LTD	No. 8, Lanxiang Road, Wujin Economic Development Zone, 213161 Jiangsu, Trung Quốc	CHINA

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