

THÔNG TIN

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

Số công bố: 220002004/PCBB-HCM

Ngày công bố: 10/06/2022

1. Tên cơ sở công bố: CÔNG TY TNHH VIỆT HÙNG GROUP
2. Địa chỉ: 68 Nguyễn Huệ, Phường Bến Nghé, Quận 1, Thành phố Hồ Chí Minh
3. Số văn bản của cơ sở: 08/2022-VHG-HIGHNESS Ngày: 08/06/2022
4. Trang thiết bị y tế thuộc loại B
Tên trang thiết bị y tế: Bộ vật liệu cấy ghép răng
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:
Mục đích sử dụng: Sử dụng hỗ trợ khám và điều trị trong nha khoa
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: HIGHNESS CO., LTD
Địa chỉ chủ sở hữu: 101, Structure 1 Daegu TechnoPark Venture Factory. 62 Seongseogongdan-ro 11-gil, DalSeogu, Deagu, Korea
7. Thông tin về cơ sở bảo hành (nếu có):
Tên cơ sở: CÔNG TY TNHH VIỆT HÙNG GROUP
Địa chỉ: 68 Nguyễn Huệ, Phường Bến Nghé, Quận 1, TP. HCM, Phường Bến Nghé, Quận 1, Thành phố Hồ Chí Minh

Điện thoại cố định: 0901447969 Điện thoại di động: 0901447969

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 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	Cây vận thân răng	SMUC100	SMUC100		HIGHNESS CO., LTD	101, Structure 1 Daegu TechnoPark Venture Factory. 62 Seongseogongdan-ro 11-gil, DalSeogu, Deagu, Korea	KOREA, REPUBLIC OF
2	Khóa thân răng nha khoa	SLZA4514, SLZA4524, SLZA4534, SLZA4544, SLZA4554, SLZA5514, SLZA5524, SLZA5534, SLZA5544, SLZA5554, SLZA6514, SLZA6524, SLZA6534, SLZA6544, SLZA6554	SLZA4514, SLZA4524, SLZA4534, SLZA4544, SLZA4554, SLZA5514, SLZA5524, SLZA5534, SLZA5544, SLZA5554, SLZA6514, SLZA6524, SLZA6534, SLZA6544, SLZA6554		HIGHNESS CO., LTD	101, Structure 1 Daegu TechnoPark Venture Factory. 62 Seongseogongdan-ro 11-gil, DalSeogu, Deagu, Korea	KOREA, REPUBLIC OF
3	Nắp đậy lạnh thương dùng trong nha khoa	SCS100-21, SCS100, SBCS100, HBC453, HBC553, HBC653, SBCSM100, HBC455, HBC555, HBC655, SMUHC100	SCS100-21, SCS100, SBCS100, HBC453, HBC553, HBC653, SBCSM100, HBC455, HBC555, HBC655, SMUHC100		HIGHNESS CO., LTD	101, Structure 1 Daegu TechnoPark Venture Factory. 62 Seongseogongdan-ro 11-gil, DalSeogu, Deagu, Korea	KOREA, REPUBLIC OF
4	Ốc vận thân răng	SMUCS100	SMUCS100		HIGHNESS CO., LTD	101, Structure 1 Daegu TechnoPark Venture Factory. 62 Seongseogongdan-ro 11-gil, DalSeogu, Deagu, Korea	KOREA, REPUBLIC OF
5	Thân răng nha khoa	SCA4515-21, SCA4525-21, SCA4535-21, SCA4545-21, SCA4555-21, SCA4517-21, SCA4527-21, SCA4537-21, SCA4547-21, SCA4557-21, SCN4515-21, SCN4525-21, SCN4535-21, SCN4545-21, SCN4555-21, SCN4517-21, SCN4527-21, SCN4537-21, SCN4547-21, SCN4557-21, SAAH451015-21, SAAH452015-21,	SCA4515-21, SCA4525-21, SCA4535-21, SCA4545-21, SCA4555-21, SCA4517-21, SCA4527-21, SCA4537-21, SCA4547-21, SCA4557-21, SCA4515-21, SCA4525-21, SCA4535-21, SCA4545-21, SCA4555-21, SCA4517-21, SCA4527-21, SCA4537-21, SCA4547-21,		HIGHNESS CO., LTD	101, Structure 1 Daegu TechnoPark Venture Factory. 62 Seongseogongdan-ro 11-gil, DalSeogu, Deagu, Korea	KOREA, REPUBLIC OF

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7	Vít vặn thân răng nha khoa	SAS100, IAS100S, IAS100, IAS200, SMUAM100, SMUAS100, 01-S, 02-S, SASM100, SAS100-17, SAS100-23	SAS100, IAS100S, IAS100, IAS200, SMUAM100,		HIGHNESS CO., LTD	101, Structure 1 Daegu TechnoPark Venture Factory. 62 Seongseogongdan-ro 11-gil, DalSeogu, Deagu, Korea	KOREA, REPUBLIC OF

			SMUAS100, 01-S, 02-S, SASM100, SAS100-17, SAS100-23				
8	Xi lanh dùng trong phục hình	SMUCP100, SMUCT100	SMUCP100, SMUCT100		HIGHNESS CO., LTD	101, Structure 1 Daegu TechnoPark Venture Factory. 62 Seongseogongdan-ro 11-gil, DalSeogu, Deagu, Korea	KOREA, REPUBLIC OF