

THÔNG TIN

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

Số công bố: 220002574/PCBB-HN

Ngày công bố: 28/07/2022

1. Tên cơ sở công bố: CÔNG TY TNHH NHA KHOA BẢO CHÂU
 2. Địa chỉ: Số 151, Phố Phương Mai, Phường Phương Mai, Quận Đống Đa, Thành phố Hà Nội
 3. Số văn bản của cơ sở: 02CBB/BC Ngày: 27/07/2022
 4. Trang thiết bị y tế thuộc loại B
Tên trang thiết bị y tế: Sứ nha khoa
Tên thương mại: Dental Ceramics
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: Dùng tạo hình răng giả
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: Tiêu chuẩn nhà sản xuất
 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: Audent AG
Địa chỉ chủ sở hữu: Landstrasse 109, FL-9495 Triesen, Liechtenstein
 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:
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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	Phôi sứ nén nha khoa	56013,56033,56053,56063,56073,56083,56093,56103,56113,56123,56133,56143,56153,56163,56173,56183,56193,56203,56213,57013,57023,57033,57043,57063,57083,57093,57103,57113,57123,57133,57143,57153,57163,57173,57183,57223,57233,57243,57253,57263,AHT56033, AHT57083,AHT57253, AHT56023, 56043.57053, 56223,56233,56243,56253,56263,56303,56313,56323, 56273,56283,56293,57193,57203,57213			estetic ceram ag	Landstrasse 109, FL-9495 Triesen, Liechtenstein	GERMANY
2	Sứ đắp nha khoa	810103,810203,810303,810403,810503,810603,810803,810903,811003,811103,811203,811303,811403,811503,811603,811703,811803,811903,813003,813203,813403, 914010,91411,914210,914310,914410, 914510,810105.810805,820115,820215,820315,820415,820515,820615,820815,820915,821015,821115,821025,821315,821415,821515,821615,821715,821815,821915,830115,830215,830315,830415,830515,830615,830815,830915, 831015,831115,831150,831215,831315,831415,831515,831615,831715,831815,831915,832015,8401100,8402100,8403100,8404100,8405100,8406100,8408100,8409100,8410100,8411100,8412100,8413100,8414100,8415100,8416100,8417100,8418100,8419100,840120,84022,840320,840420,840520,840620,840820,840920,841020,841120,841220,841320,841420,841520,841620,841720,841820,841920,840150,840250,840350,840450,840550,840650,840850,840950,841050,841150,841250,841350, 841450,841550,841650,841750,841850,841950,842120,842220,84200,842150,84225,842300,843015,843115,843215,843315,843415,843515,843615,843715,845120,845220,new,new,new, 847115,847215,847315,847415,8501100,8503100,8502100,8504100,850120, 850220,850320,850420,850150,85025			estetic ceram ag	Landstrasse 109, FL-9495 Triesen, Liechtenstein	GERMANY

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