

**THÔNG TIN**

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

**Số công bố: 220001673/PCBB-HCM**

**Ngày công bố: 24/05/2022**

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1. Tên cơ sở công bố: CÔNG TY TNHH NHA KHOA THÁI BÌNH DƯƠNG

2. Địa chỉ: 22-24 Nguyễn Văn Thủ, phường Đa Kao, Quận 1, thành phố Hồ Chí Minh, Phường Đa Kao, Quận 1, Thành phố Hồ Chí Minh

3. Số văn bản của cơ sở: 017.22/TBD/NKB Ngày: 19/05/2022

4. Trang thiết bị y tế thuộc loại B

Tên trang thiết bị y tế: Bột sứ đắp răng giả & dung dịch trộn bột sứ

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: Phục hình răng giả để gắn cho bệnh nhân

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: ISO13485:2016

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: WOHLWEND AG

Địa chỉ chủ sở hữu: Platta 52, FL-9488 Schellenberg

7. Thông tin về cơ sở bảo hành (nếu có):

Tên cơ sở: Công ty TNHH Nha Khoa Thái Bình Dương

Địa chỉ: 22-24 Nguyễn Văn Thủ, Phường Đa Kao, Quận 1, Thành phố Hồ Chí Minh

Điện thoại cố định: 84-8-39112170 Điện thoại di động:

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	Bản tiêu chuẩn mà chủ sở hữu trang thiết bị y tế công bố áp dụng	x
6	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	Bột sứ đắp răng giả	Vision-Classic Opaquer AB-0 1033; 1034, Vision-Classic Opaquer A1 101; 102;426, Vision-Classic Opaquer A2 103;104;427, Vision-Classic Opaquer A3 105;106;428, Vision-Classic Opaquer A3,5 107;108;429, Vision-Classic Opaquer A4 109;110;430, Vision-Classic Opaquer B1 111;112; 431, Vision-Classic Opaquer B2 113; 114;432, Vision-Classic Opaquer B3 115;116;433, Vision-Classic Opaquer B4 117;118;434, Vision-Classic Opaquer C1 119;120;435, Vision-Classic Opaquer C2 121;122;436, Vision-Classic Opaquer C3 123;124; 437, Vision-Classic Opaquer C4 125; 126;438, Vision-Classic Opaquer D2 127;128;439, Vision-Classic Opaquer D3 129;130;440, Vision-Classic Opaquer D4 131;132;441, Vision-Classic Opaquer Repair 451, Vision-Classic Opaquer Gingiva 604;605, Vision-Classic Opak-Dentin A0 1039; 1040, Vision-Classic Opak-Dentin A1 133;134, Vision-Classic Opak-Dentin A2 135;136, Vision-Classic Opak-Dentin A3 137;138, Vision-Classic Opak-Dentin A3,5 139;140, Vision-Classic Opak-Dentin A4 141;142, Vision-Classic Opak-Dentin B0 1041; 1042, Vision-Classic Opak-Dentin B1 143;144, Vision-Classic Opak-Dentin B2 145;146, Vision-Classic Opak-Dentin B3 147;148, Vision-Classic Opak-Dentin B4 149;150, Vision-Classic Opak-Dentin C1 151;152, Vision-Classic Opak-Dentin C2 153; 154, Vision-Classic Opak-Dentin C3 155;156, Vision-Classic Opak-Dentin C4 157;158, Vision-Classic Opak-Dentin D2 159;160, Vision-Classic Opak-Dentin D3 161;162, Vision-Classic Opak-Dentin D4 163;164, Vision-Classic Dentin A0 1035;1036, Vision-Classic Dentin A1 165;166;167, Vision-Classic Dentin A2 168;169;170, Vision-Classic Dentin A3 171;172;173,			WOHLWEND AG	Platta 52, FL-9488 Schellenberg	LIECHTENSTEIN

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2	Dung dịch trộn bột sứ	<p>Vision-Classic Modeling&amp;Effect Liquid 289;290;291;292;300, Vision-Classic Modeling Liquid Repair 456, Vision-Classic Opaquer Liquid 293; 294;295;442, Vision-Classic Opaquer Liquid Repair 457, Vision-Classic Opaquer Liquid -2 470;471;472, Vision-Classic Glaze &amp; Stain Liquid 296;297;418;419, Vision-Classic Shoulder Liquid 298;299</p>			WOHLWEND AG	Platta 52, FL-9488 Schellenberg	LIECHTENSTEIN
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5	Dung dịch trộn bột sứ	Vision-Zirkon Modeling Liquid 2220; 2221;2222;2223, Vision-Zirkon Glaze & Stain Liquid 2225;2226;2227, Vision-Zirkon Shoulder Liquid 2230; 2231;2232			WOHLWEND AG	Platta 52, FL-9488 Schellenberg	LIECHTENSTEIN
6	Bột sứ đắp răng giả	Vision-Zirkon Assortment S1 2300, Vision-Zirkon Assortment S2 2301, Vision-Zirkon Assortment S3 2302, Vision-Zirkon Assortment S4 2305, Vision-Zirkon Assortment S5 2307, Vision-Zirkon Stain- Assortment 2303, Vision-Zirkon Testkit 2304, Vision-Zirkon Shade guide Dentin 2490, Vision-Zirkon Shade guide Incisal 2491, Vision-Zirkon Shade guide Transpa 2492, Vision-Zirkon Shade guide Shoulder/OD/G 2493, Vision-Zirkon Shade guide Chroma/Mamelon 2494, Vision-Zirkon Shade guide Bleach 2495			WOHLWEND AG	Platta 52, FL-9488 Schellenberg	LIECHTENSTEIN
7	Bột sứ đắp răng giả	Vision-3D Artistic Shade A 740, Vision-3D Artistic Shade B 741, Vision-3D Artistic Shade C 742, Vision-3D Artistic Shade D 743, Vision-3D Artistic Stain White 744, Vision-3D Artistic Stain Honey 745,			WOHLWEND AG	Platta 52, FL-9488 Schellenberg	LIECHTENSTEIN



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8	Bột sứ đắp răng giả	<p>Vision-Universal Glaze-Paste 373, Vision-Universal Glaze 693;694;695, Vision-Universal Stain Powder A 700, Vision-Universal Stain Powder B 701, Vision-Universal Stain Powder C 702, Vision-Universal Stain Powder D 703, Vision-Universal Stain Powder White 704, Vision-Universal Stain Powder Honey 705, Vision-Universal Stain Powder Olive 706, Vision-Universal Stain Powder Redbrown 707, Vision-Universal Stain Powder Chestnut 708, Vision-Universal Stain Powder Grey 709, Vision-Universal Stain Powder Blue 710, Vision-Universal Stain Powder Glaze 711, Vision-Universal Stain Powder Red 728, Vision-Universal Stain Powder Pink 729, Vision-Universal Stain Powder Assortment 726, Vision-Universal Stain-Paste A 712, Vision-Universal Stain-Paste B 713, Vision-Universal Stain-Paste C 714, Vision-Universal Stain-Paste D 715, Vision-Universal</p>			WOHLWEND AG	Platta 52, FL-9488 Schellenberg	LIECHTENSTEIN

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