

VĂN BẢN CÔNG KHAI

Nội dung và hình thức dự kiến quảng cáo thiết bị y tế

Kính gửi: Cục Hạ tầng và Thiết bị y tế - Bộ Y tế

1. Tên cơ sở công khai: CÔNG TY CỔ PHẦN THƯƠNG MẠI VÀ DỊCH VỤ KỸ THUẬT TÂN KHANG

Mã số thuế: 0318277525

Địa chỉ: Số 314/6 Đường Điện Biên Phủ, Phường Vườn Lài, Thành phố Hồ Chí Minh

Điện thoại: 02862926585

Fax:

Email: ngubt@tkmedical.vn

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2. Người đại diện hợp pháp của cơ sở:

Họ và tên: Nguyễn Quỳnh An

Số căn cước/Hộ chiếu: 060189000472 ngày cấp: 22/11/2021 nơi cấp: Cục Cảnh Sát QLHC về TTXH

Điện thoại cố định: 0774135346

Điện thoại di động: 0911308410

3. Thông tin về thiết bị y tế dự kiến quảng cáo:

- Tên thiết bị y tế: Vi ống thông dùng trong can thiệp mạch

- Chung loại: Theo phụ lục

- Mã sản phẩm (nếu có): Theo phụ lục

- Hãng sản xuất: Theo phụ lục

- Nước sản xuất: Theo phụ lục

- Số lưu hành: 2503833ĐKLH/HTTB-ĐKKD

- Tính năng, tác dụng: Vi ống thông dùng trong can thiệp mạch Distail™ Microcatheter được thiết kế để bơm truyền có kiểm soát và chọn lọc các chất và thiết bị chẩn đoán, gây tắc mạch hoặc điều trị vào các mạch máu đích trong hệ thống mạch máu ngoại biên. Distail™ Microcatheter không được thiết kế để sử dụng cho mạch máu não và mạch vành.

- Tên, địa chỉ của chủ sở hữu số lưu hành thiết bị y tế: CÔNG TY CỔ PHẦN THƯƠNG MẠI VÀ DỊCH VỤ KỸ THUẬT TÂN KHANG, Số 314/6 Đường Điện Biên Phủ, Phường Vườn Lài, Thành phố Hồ Chí Minh

- Cảnh báo liên quan đến sức khỏe người sử dụng, điều kiện bảo quản (nếu có): Theo hướng dẫn sử dụng của sản phẩm

Chúng tôi công khai nội dung và hình thức dự kiến quảng cáo đối với thiết bị y tế như sau:

Nội dung dự kiến quảng cáo:

Theo tài liệu đính kèm

Hình thức dự kiến quảng cáo:

Không phải báo nói báo hình, Hội thảo

Cơ sở cam kết:

1. Nội dung thông tin công khai là chính xác, hợp pháp và theo đúng quy định. Nếu có sự giả mạo, không đúng sự thật cơ sở xin chịu hoàn toàn trách nhiệm và sẽ bị xử lý theo quy định của pháp luật.
2. Bảo đảm nội dung quảng cáo phù hợp với bản nội dung dự kiến quảng cáo đã công khai và hồ sơ công bố tiêu chuẩn áp dụng đối với thiết bị y tế thuộc loại A, B hoặc hồ sơ đăng ký lưu hành đối với thiết bị y tế thuộc loại C, D.

Người đại diện hợp pháp của cơ sở

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 |
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