

THÔNG TIN

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

Số công bố: 260001304/PCBB-HCM

Ngày công bố: 11/05/2026

1. Tên cơ sở công bố: CÔNG TY CỔ PHẦN THƯƠNG MẠI VÀ KỸ THUẬT GIA HÂN
2. Địa chỉ: 19/1E Trần Bình Trọng, Phường Bình Lợi Trung, Thành phố Hồ Chí Minh
3. Số văn bản của cơ sở: 040526-GH-SJ-ELIX Ngày: 04/05/2026
4. Thiết bị y tế thuộc loại B
Tên thiết bị y tế: Ống dẫn lưu đa chức năng ELIX™
Tên thương mại (nếu có):
Mã Global Medical Device Nomenclature – GMDN (nếu có):
Chủng loại: ELIX™ Multipurpose Drainage Catheter

Mã sản phẩm (nếu có):

DCS8.5B-P20-15-5S; DCS10.2B-P20-15-5S; DCS12B-P20-15-5S; DCS8.5B-P20-25-5S; DCS10.2B-P20-25-5S; DCS12B-P20-25-5S; DCS8.5B-P20-40-5S; DCS10.2B-P20-40-5S; DCS12B-P20-40-5S; DCS8.5B-P10-15-5S; DCS10.2B-P10-15-5S; DCS12B-P10-15-5S; DCS8.5B-P10-25-5S; DCS10.2B-P10-25-5S; DCS12B-P10-25-5S; DCS8.5B-P10-40-5S; DCS10.2B-P10-40-5S; DCS12B-P10-40-5S; DCS8.5B-P05-15-5S; DCS10.2B-P05-15-5S; DCS12B-P05-15-5S; DCS8.5B-P05-25-5S; DCS10.2B-P05-25-5S; DCS12B-P05-25-5S; DCS8.5B-P05-40-5S; DCS10.2B-P05-40-5S; DCS12B-P05-40-5S; PCNS8.5B-P20-25-5S; PCNS10.2B-P20-25-5S; PCNS12B-P20-25-5S; PCNS8.5B-P10-25-5S; PCNS10.2B-P10-25-5S; PCNS12B-P10-25-5S; PCNS8.5B-P05-25-5S; PCNS10.2B-P05-25-5S; PCNS12B-P05-25-5S; DCS8.5HC-P20-15-5S; DCS10.2HC-P20-15-5S; DCS12HC-P20-15-5S; DCS8.5HC-P20-25-5S; DCS10.2HC-P20-25-5S; DCS12HC-P20-25-5S; DCS8.5HC-P20-40-5S; DCS10.2HC-P20-40-5S; DCS12HC-P20-40-5S; DCS8.5HC-P10-15-5S; DCS10.2HC-P10-15-5S; DCS12HC-P10-15-5S; DCS8.5HC-P10-25-5S; DCS10.2HC-P10-25-5S; DCS12HC-P10-25-5S; DCS8.5HC-P10-40-5S; DCS10.2HC-P10-40-5S; DCS12HC-P10-40-5S; DCS8.5HC-P05-15-5S;

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DCF12B-P20-25-5S; DCF8.5B-P10-25-5S; DCF8.5B-P10-25-9S; DCF10.2B-
P10-25-5S; DCF10.2B-P10-40-5S; DCF8.5B-P05-25-5S; DCS8.5HC-P20-25-
5S-NS; DCS10.2HC-P20-25-5S-NS; DCF12HC-P20-25-5S; DCS12HC-P20-
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P10-25-5S; DCS10.2HC-P10-25-5S-NS; DCS12HC-P10-25-5S-NS;
DCS8.5HM-P20-31-20S; DCS10.2HM-P20-31-20S; DCS12HM-P20-31-20S;
DCF10.2HM-P20-40-20S; DCS8.5HM-P10-31-20S; DCS10.2HM-P10-31-
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DCF10.2B-DP-29-19S; DCF8.5HC-DP-29-19S; DCF10.2HC-DP-29-19S;
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Quy cách đóng gói:

Mục đích sử dụng: Ống dẫn lưu đa chức năng ELIX™ được chỉ định sử dụng cho dẫn lưu qua da trong nhiều ứng dụng khác nhau, bao gồm nhưng không giới hạn ở dẫn lưu đường mật, áp xe, dẫn lưu thận và chọc hút dịch. Thiết bị này được thiết kế cho mục đích sử dụng ngắn hạn (dưới 30 ngày).

Tên cơ sở sản xuất: SUNGJIN-HITECH CO., LTD

Địa chỉ cơ sở sản xuất: 211 – 9, Gajang-ro, Jeongnam-myeon, Hwaseong-si, Gyeonggi-do, KOREA, REPUBLIC OF

Tiêu chuẩn chất lượng sản phẩm áp dụng: Tiêu chuẩn của nhà sản xuất

5. Đối với thiết bị y tế chứa chất ma túy, tiền chất (nếu có):

6. Thông tin về chủ sở hữu thiết bị y tế:

Tên chủ sở hữu: SUNGJIN-HITECH CO., LTD

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

8. Số công bố đủ điều kiện sản xuất đối với thiết bị y tế sản xuất trong nước:

9. Thành phần hồ sơ:

1	Văn bản công bố tiêu chuẩn áp dụng của 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 thiết bị y tế	x
4	Giấy xác nhận đủ điều kiện bảo hành	x
5	Tài liệu mô tả tóm tắt kỹ thuật thiết bị y tế bằng tiếng Việt, kèm theo tài liệu kỹ thuật mô tả chức năng, thông số kỹ thuật của thiết bị y tế do chủ sở hữu thiết bị y tế ban hành.	x
6	Giấy chứng nhận hợp chuẩn hoặc bản tiêu chuẩn mà chủ sở hữu thiết bị y tế công bố áp dụng	x
7	Giấy chứng nhận lưu hành tự do còn hiệu lực tại thời điểm nộp hồ sơ đối với thiết bị y tế nhập khẩu.	x