China Leading Closed-System Intermittent Catheter: DAXAN Duro-Pocket® Product Line and OEM ODM Services for Buyers

CHENGDU, SICHUAN, CHINA, July 29, 2026 /EINPresswire.com/ -- For healthcare distributors and medical device importers evaluating the intermittent catheterization market, the selection of a Closed-System Intermittent Catheter Manufacturer has become less about product variety and more about the structural integrity of the hygiene architecture supporting it. Contamination during catheter insertion remains the primary driver of catheter-associated urinary tract infections among patients who rely on intermittent catheterization daily, and open-system handling is the weakest point in that chain. Sourcing from a closed-system catheter manufacturer that integrates no-touch design, pre-hydration, and collection into a sealed unit addresses the problem at its source. Chengdu Daxan Innovative Medical Tech Co., Ltd. (DAXAN), established in 2016 and operating with more than nine years of hydrophilic catheter research and production experience, has built the Duro-Pocket® product line around exactly this principle, combining closed-system engineering with CE MDR 2017/745 and dual FDA 510(k) market clearance to give importers and distributors a supply partner with a verified compliance foundation.

Why Closed-System Catheters Are Now a Baseline Buyer Requirement

Patients who perform intermittent catheterization several times daily face a substantially elevated risk of urinary tract infection when the catheter surface makes uncontrolled contact with the surrounding environment. The design logic of a closed-system catheter is to eliminate that variable: by enclosing the catheter body, the hydrophilic coating activation, and a urine collection bag within a single sealed unit, insertion can proceed without the catheter touching external surfaces at any point. This is not an incidental product feature. It is a structural approach to managing infection risk at the device level.

For procurement teams and distributor buyers evaluating supplier capabilities, the closed-system designation has become an early-stage filter. Buyers are asking not only whether the coating performs but whether the entire system maintains sterility without requiring additional preparation steps. DAXAN addresses both sides of that question through the Duro-Pocket® line, which offers two distinct activation formats -- ready-to-use prehydration and water sachet activation -- allowing distributors to align SKU selection with the clinical preferences and market expectations of the patients they serve.

Duro-Pocket® RTU: Prehydrated No-Touch Closed-System Catheter for Immediate Sterile Use

The Duro-Pocket® RTU catheter is engineered around the principle that no preparation step should introduce contamination risk. The product is prehydrated from manufacture: once the packaging is opened, the catheter is ready for insertion with no additional lubrication or water activation required. A convenient pull ring removes the protective cap from the introducer tip in a single motion, without direct contact with the catheter body. The no-touch closed-system design is covered by DAXAN Patent No. ZL201821674844.4.

The fully enclosed no-touch introducer tip maintains a sterile interface throughout the insertion process. Fire-polished side eyelets reduce mucosal friction and minimize the potential for tissue irritation. The catheter body is made from medical-grade TPU, soft and flexible to conform to the natural contours of the urethra. An integrated 1300 mL urine collection bag accommodates full bladder drainage in home, travel, and clinical settings.

Size availability spans pediatric through adult populations: pediatric sizes in 6 to 14FR, female adult sizes in 8 to 18FR, and male adult sizes in 8 to 18FR. Packaging is supplied at 30 units per box and 300 units per carton, aligning with standard distributor and hospital procurement quantities.

Duro-Pocket® with Water Sachet: Four Tip Configurations and Dual Material Options for Distributor Flexibility

The Duro-Pocket® Water Sachet variant activates the patented Coatapex™ Hydrolyx™ hydrophilic coating (Patent No. ZL201811203221.3) using a sterile saline sachet, reaching full lubricity within approximately 60 seconds. This format suits users and markets that prefer an activation step

before insertion, providing confidence that the coating is fully hydrated before the procedure begins. Like the RTU variant, the product operates as a closed touch-free system, reducing direct manual contact with the catheter surface throughout insertion. The integrated 1300 mL collection bag and compact, discreet packaging make the product adaptable to home, workplace, and travel settings.

Where the Water Sachet variant is particularly valuable for distributor programs is the breadth of its tip configuration options. Four tip types -- straight, ball, soft, and Tiemann -- allow a single supplier relationship to address the anatomical and clinical requirements of diverse patient populations. Catheter body material is available in both PVC and TPU, providing a further dimension of customization for buyers building regional or private-label product lines.

OEM ODM Services: Custom Closed-System Catheter Manufacturing for Global Importers and Distributors

DAXAN provides OEM and ODM manufacturing services across the Duro-Pocket® line and the broader intermittent catheter range. Customization is available across FR sizes from CH06 to CH24, multiple catheter lengths, four tip configurations, PVC or TPU material selection, and private labeling with custom packaging design. Importers and device brand owners can consolidate product specification, regulatory documentation, and manufacturing sourcing through a single verified supplier, avoiding the coordination overhead and delivery uncertainty that comes with multi-vendor programs.

Reliable OEM delivery in the closed-system catheter category depends on three intersecting capabilities: an ISO 13485:2016-certified production environment, confirmed market-access registrations in the target distribution regions, and production capacity sufficient to meet framework orders and volume growth without supply interruption. At Chengdu Daxan Innovative Medical Tech Co., Ltd., that means a 6,000 square meter dedicated cleanroom and integrated testing center, dual FDA 510(k) clearance alongside CE MDR 2017/745 registration, and an annual output exceeding 20 million catheter units.

Manufacturing Credentials: ISO 13485 Cleanroom, CE MDR, Dual FDA 510(k) Clearance, and 20M Annual Capacity

The compliance architecture behind the Duro-Pocket® product line rests on four verifiable credentials. ISO 13485:2016 certification covers the full quality management system and underpins all downstream product registrations. CE Marking under EU MDR 2017/745 (Full Quality Assurance) provides access to EU and EEA markets for importers subject to European device regulations. Two FDA 510(k) clearances -- K212567, covering hydrophilic intermittent catheters, and K243175, covering the TPU product line -- establish US market access under FDA-reviewed submissions. China NMPA registration, a Free Sale Certificate, and a CCPIT Certificate of Origin complete the documentation package for importers across Asia and additional export markets.

These credentials allow importers to proceed through internal qualification and regulatory submission processes without supplemental testing or additional compliance documentation from the manufacturer. DAXAN exports products to more than 25 countries and has maintained an active presence in the international medical device market since its founding in 2016. The company's closed-system intermittent catheter line is produced entirely within the ISO 13485:2016 certified cleanroom facility in Chengdu, supported by advanced extrusion, molding, and packaging technologies.

Importers, device brand owners, and distributors seeking product specifications, OEM program details, or regulatory documentation for the Duro-Pocket® closed-system catheter line are invited to connect with the team through the official website at https://www.daxanmedical.com/. Reliable, documented, and scalable supply for closed-system intermittent catheters starts with a manufacturer whose engineering and compliance foundations are already in place.

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