DAXAN China-Leading Closed-System Catheter Manufacturer: Duro-Pocket® with No-Touch Introducer Tip

CHENGDU, SICHUAN, CHINA, July 29, 2026 /EINPresswire.com/ -- For procurement teams evaluating urinary catheter supply chains, catheter-associated urinary tract infection (CAUTI) risk has moved from clinical concern to a formal sourcing criterion. Whether a catheter design eliminates direct contact between the catheter surface and the external environment is now among the first questions distributors and importers ask when qualifying new suppliers. A Closed-System Catheter Manufacturer, in the context of B2B medical device procurement, is a manufacturer capable of providing a sealed catheter assembly that cuts external contamination pathways throughout the catheterization sequence, and of substantiating that capability through auditable production documentation and regulatory clearance. Chengdu Daxan Innovative Medical Tech Co., Ltd. has developed the Duro-Pocket® product line with this standard at its center. This press release outlines the design rationale, technical specifications, regulatory credentials, and supply capabilities of the Duro-Pocket® closed-system catheter range.

Why Closed-System Catheter Design Defines Modern Procurement Standards

The structural distinction between a closed-system and an open-system intermittent catheter is not cosmetic. In an open-system design, the catheter surface is exposed to the environment during handling and insertion. In a closed system, the catheter assembly, introducer tip, drainage bag, and lubrication mechanism form an integrated sealed unit, limiting external contact at each step of the catheterization sequence. For CAUTI prevention, the critical exposure points are pre-insertion handling and the moment of urethral entry. Closed-system architecture addresses both simultaneously.

Regulatory expectations in major import markets have reinforced this procurement shift. The EU Medical Device Regulation 2017/745 places heightened documentation requirements on device performance consistency over the product lifecycle. The FDA 510(k) pathway requires demonstrated performance evidence before US market entry.

The Duro-Pocket® line holds CE marking under EU MDR 2017/745 and FDA 510(k) clearances K212567 and K243175, giving distribution partners a dual-market compliance foundation that can be verified through publicly accessible regulatory databases.

DAXAN's Duro-Pocket® No-Touch Introducer Tip: Engineering Design and Sterility Rationale

The Duro-Pocket® RTU ready-to-use catheter is built around a fully enclosed no-touch introducer tip. This design maintains sterility throughout the insertion process, a feature directly relevant to CAUTI risk reduction for high-frequency users such as patients managing neurogenic bladder or spinal cord injury. The introducer tip remains sealed until use, eliminating the pre-insertion handling step that represents the primary contamination opportunity in conventional catheter procedures. The no-touch introducer tip is part of DAXAN’s patented Duro-Pocket® closed system (Patent No. ZL201821674844.4), and its activation-free hydrophilic coating technology is covered by Patent No. ZL201811203221.3.

A convenient pull ring enables quick removal of the protective cap from the pre-lubricated introducer tip, so the complete catheterization sequence requires no additional preparation steps. The catheter body is manufactured from medical-grade TPU, a soft, flexible material that adapts to the natural contours of the urethra. The Duro-Pocket® RTU is available in Pediatric sizes from 6 to 14 FR, Female sizes from 8 to 18 FR, and Male sizes from 8 to 18 FR, packaged at 30 units per box and 300 units per carton. The catheter arrives prehydrated; no additional lubrication is required before use.

Fire-Polished Eyelets, 1300 mL Integrated Bag, and Prehydrated Configuration: The Complete Closed-System Architecture

Three coordinated design features complete the Duro-Pocket® sealed system. Fire-polished eyelets along the catheter shaft minimize mucosal friction and irritation during insertion and withdrawal, reducing the potential for tissue damage and the infection risk associated with it. An

integrated urine collection bag with a capacity of up to 1,300 mL accepts drainage directly without requiring the catheter to be separated from collection equipment before the procedure concludes. The catheter is supplied prehydrated and ready to use, removing the lubrication step where contamination could otherwise be introduced.

Together, these elements form a complete sealed sequence from package opening to procedure completion: enclosed introducer tip, prehydrated catheter body, fire-polished eyelets, and integrated collection bag, each step requiring no additional contact with the catheter surface or drainage output. For distributors needing broader tip configuration options, the Duro-Pocket® Water Sachet variant replaces the prehydrated format with a sterile saline sachet that activates in approximately 60 seconds. This variant offers four tip types (straight, ball, soft, and Tiemann) in PVC or medical-grade TPU, in the same 30-unit and 300-unit packaging formats.

DAXAN's Manufacturing Foundation: ISO 13485 Cleanroom, Dual FDA 510(k), and CE MDR Credentials

The Duro-Pocket® line is manufactured in a facility holding ISO 13485:2016 certification, with more than 6,000 square meters of cleanroom production and integrated testing space. DAXAN produces more than 20 million hydrophilic catheters annually across this facility, providing the batch consistency and order volume capacity that framework-contract buyers and large-volume distributors require.

The Duro-Pocket® series holds CE marking under EU MDR 2017/745 via the Full Quality Assurance route, FDA 510(k) clearances K212567 and K243175, and China NMPA registration. FDA Establishment Registration FEI 3023329815 is independently verifiable through the FDA database, and both K-numbers can be queried directly in the FDA 510(k) database. This combination of EU, US, and China regulatory coverage from a single source reduces the compliance steps an importer must complete before entering multiple regional markets.

OEM Customization and Global Supply Capability for Distributors and Importers

Chengdu Daxan Innovative Medical Tech Co., Ltd. offers OEM and ODM customization across the Duro-Pocket® line and the wider catheter portfolio. Configuration options include choice of material (PVC or medical-grade TPU), FR sizes spanning CH06 through CH24, multiple length configurations, and private-label packaging. Because the triple-market regulatory framework is already in place, OEM buyers can structure private-label arrangements within the existing compliance architecture rather than initiating a new product registration from the beginning.

Annual production capacity exceeding 20 million units supports both framework orders and large-volume supply agreements. Products from the DAXAN closed-system catheter range currently reach distribution partners across more than 25 countries, a supply footprint that reflects both manufacturing scale and multi-market documentation readiness.

Established in 2016 and active in the hydrophilic catheter segment for more than nine years, Chengdu Daxan Innovative Medical Tech Co., Ltd. has built its closed-system catheter manufacturer position on a combination of sealed-system engineering, auditable regulatory compliance, and ISO 13485:2016 production infrastructure. For importers, distributors, and OEM buyers qualifying a closed-system catheter source, the enclosed no-touch introducer tip design, dual FDA 510(k) clearances, CE MDR 2017/745 certification, and annual capacity exceeding 20 million units represent a verifiable qualification baseline. Trusted Technology, Global Compliance, Reliable Supply. Product specifications, certification documentation, and OEM inquiry channels are available at www.daxanmedical.com.

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