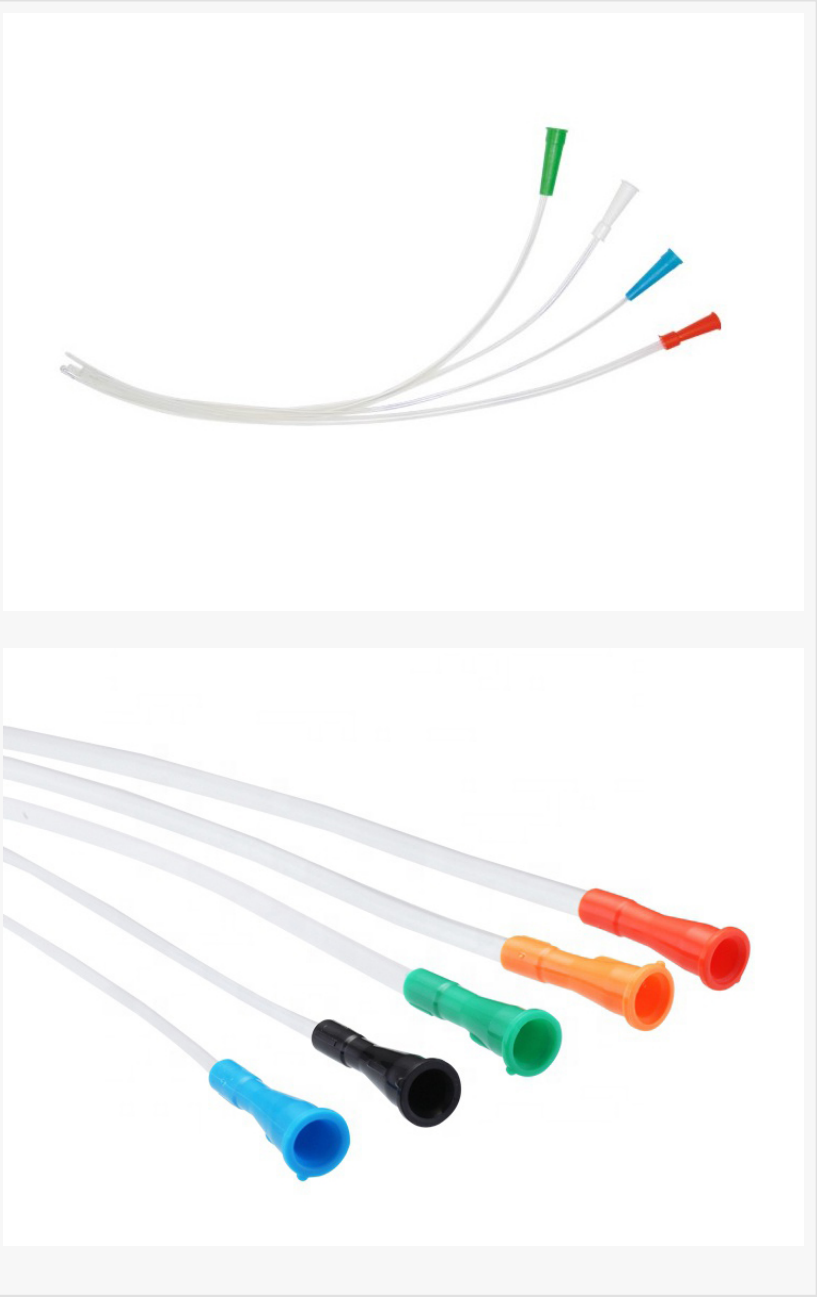
China Top Urology Catheter Manufacturer DAXAN with ISO 13485 Facility and OEM ODM Services for Distributors



CHENGDU, SICHUAN, CHINA, July 29, 2026 /EINPresswire.com/ -- For medical device distributors consolidating their urology supply chain, the vendor qualification checklist rarely stops at a single SKU. It extends production capacity, cleanroom certification, multi-market regulatory clearances, and the ability to source under a private label — ideally from one manufacturer. Finding a urology catheter manufacturer that satisfies all four criteria from a single production source is the central procurement challenge for regional importers managing launches across multiple regulatory markets. Chengdu Daxan Innovative Medical Tech Co., Ltd. (DAXAN), headquartered in Chengdu, China, is a vertically integrated Urology Catheter Manufacturer producing five categories of urology devices from a 6,000 m² ISO 13485:2016-certified cleanroom, with annual output exceeding 20 million units and export activity spanning more than 25 countries.

This profile outlines DAXAN's product range, manufacturing infrastructure, regulatory credentials, and OEM ODM program for distributors and importers conducting supplier evaluations.

DAXAN Presents a Full-Range Urology Catheter Portfolio Spanning Five Product Categories

DAXAN's product line covers five urology device categories, offering distributors a consolidated sourcing path that spans clean intermittent catheterization, long-term indwelling drainage, and interventional urology — all from a single ISO 13485-certified manufacturer.

The intermittent catheter (IC) line is the primary category, with nine SKUs covering every major tip configuration and patient population: Nelaton straight-tip catheters in pre-lubricated and non-pouch variants, a Tiemann angled-tip option for male urethral anatomy, the DuroFlex™ flexible ball-tip ISC catheter engineered to adapt to the natural contours of the male urethra, a compact folding catheter for home and travel use, and the Duro-Pocket® closed-system line — featuring an enclosed no-touch introducer tip that reduces direct manual contact throughout the insertion process. Pediatric and adult sizes span 6 FR to 24 FR across female and male configurations.

Beyond intermittent catheters, the full portfolio includes:

Foley Catheters — two indwelling variants: 14-day latex and 28-day silicone. Note: Foley catheters are manufactured within DAXAN's ISO 13485-certified facility but do not hold independent CE MDR or FDA 510(k) clearance.
DJ Ureteral Stents — two models for upper urinary tract management.
Ureteral Access Sheaths — two configurations supporting flexible ureteroscopy procedures.
Urology Guidewires — one product line for endoscopic and interventional navigation.
All five categories are manufactured and quality-controlled within the same certified facility. For distributors, intermittent catheters, DJ stents, sheaths, and guidewires share a unified regulatory documentation trail; Foley catheters follow a separate certification pathway.

DAXAN's broader urology R&D portfolio includes an anti-reflux autonomous urination catheter (Patent No. ZL202221053356.8), drug-loaded catheter technology (Patent No. ZL202322158658.2), and a non-balloon indwelling catheter (Patent No. ZL202322320741.5). These patent references document R&D scope; they do not replace product-specific CE MDR or FDA 510(k) clearance.

ISO 13485:2016 Certified 6,000 m² Cleanroom Facility Supports Over 20 million Unit Annual Output

The manufacturing foundation for DAXAN's urology catheter range is a dedicated cleanroom facility exceeding 6,000 m², certified under ISO 13485:2016, with an integrated on-site testing center. Chengdu Daxan Innovative Medical Tech Co., Ltd. operates as an ISO 13485 urology device manufacturer from a single, purpose-built production environment — not a trading company relying on third-party contract production.

Annual production capacity stands at more than 20 million hydrophilic catheters, a throughput that supports both high-volume standing orders and the flexible batch sizes required for OEM

private-label programs across multiple regional distributors. Established in 2016, DAXAN has accumulated more than nine years of medical-grade catheter R&D and production experience, covering the full manufacturing chain: extrusion, molding, punching, and packaging — all executed within the same controlled environment.

The proprietary Coatapex™ Hydrolyx™ hydrophilic coating platform, used across the IC product line, is produced in-house. Based on a polyvinylpyrrolidone (PVP) formulation, the coating achieves a coefficient of friction (COF) as low as 0.02 and maintains stable lubricity for more than 24 hours after activation. No latex, DEHP, or BPA is present in any product line. This gives distributors a verifiable basis for the performance specifications on every shipped unit.

Triple-Market Regulatory Compliance: CE MDR 2017/745, Dual FDA 510(k), and NMPA Registration

Distributors importing medical devices into the European Union, the United States, or China face distinct regulatory requirements in each market. DAXAN holds active clearances across all three, allowing a single supplier relationship to support multi-market launches without requiring separate manufacturer qualifications for each target region.

The EU market clearance is held under CE Marking via the Full Quality Assurance pathway of EU MDR 2017/745, covering the hydrophilic intermittent catheter product line for all EU and EEA market entry. US product clearances are documented under two independent FDA 510(k) decisions: K212567, issued for the hydrophilic intermittent catheter range, and K243175, issued for the TPU intermittent catheter line — both verifiable in the FDA's public 510(k) database. The company's FDA Establishment Registration number is FEI 3023329815. China NMPA (formerly CFDA) registration covers the domestic market and provides an additional compliance layer recognized by distributors in Asian markets.

Supporting these three primary clearances are a Free Sale Certificate (FSC) covering multiple export markets and a Certificate of Origin issued by CCPIT (China Council for the Promotion of International Trade). Each clearance traces back to the same certified production system — giving distributors an integrated compliance record rather than four independently maintained quality files.

OEM ODM Services for Distributors: Custom Design and Private-Label Programs Across CH06–CH24 FR Sizes

DAXAN's OEM ODM program is designed for medical device distributors, importers, and brand owners launching private-label urology catheter lines without constructing their own manufacturing compliance infrastructure. The customization scope spans the full technical parameter set that determines product registration and clinical performance at the distribution level.

FR size availability runs from CH06 to CH24, covering pediatric, female, and adult male configurations across multiple lengths. Tip configuration options include four types: Nelaton straight, Tiemann angled, flexible ball tip, and the closed-system enclosed introducer tip from the Duro-Pocket® product family. Tube material is available in both PVC and medical-grade TPU (DEHP-free, BPA-free), with the TPU formulation certified as eco-friendly and biodegradable under natural conditions. Private labeling and custom packaging are supported across all SKUs, with standard packaging running 30 units per box and 300 units per carton, configurable to distributor specifications.

The ISO 13485:2016 manufacturing environment underpins every OEM order. A distributor launching a private-label intermittent catheter line under this program receives product manufactured and quality-controlled in the same certified cleanroom that produces DAXAN's branded range — with the same compliance documentation chain available to support importation and in-market registration. For brand owners evaluating China urology catheter OEM suppliers, this combination represents a configurable platform rather than a fixed catalog.

Products Exported to 25+ Countries Through Direct Distributor Relationships

DAXAN's export network covers more than 25 countries, supplied directly from the manufacturer to distributors and importers without an intermediate trading layer. The distribution footprint spans markets across Europe, Asia, the Americas, and beyond, backed by the multi-market regulatory clearances applicable to each product line as presented in this release.

Chengdu Daxan Innovative Medical Tech Co., Ltd. maintains active engagement with international distributors through regular participation in major industry trade fairs, staying closely attuned to evolving customer requirements and regional market trends across its export markets.

DAXAN also maintains a clinical education content library covering intermittent catheterization, neurogenic bladder management, and related urology topics, reflecting the clinical domain knowledge the company brings to distributor partnerships beyond product specifications alone.

Combining nine years of manufacturing experience with ISO 13485-certified production and triple-market regulatory clearances, Chengdu Daxan Innovative Medical Tech Co., Ltd. offers global distributors, importers, and brand owners a single-source OEM ODM partner for urology catheter sourcing.

Distributors seeking product samples, OEM customization quotes, or regulatory documentation may initiate contact at https://www.daxanmedical.com/.

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