China Leading Intermittent Catheter by DAXAN: ISO 13485 Cleanroom and 20M Annual Capacity for Urology Care

Chengdu, Sichuan Jul 24, 2026 (Issuewire.com) - Global procurement of intermittent catheters has become considerably more rigorous. Distributors and importers now evaluate suppliers not on unit price alone, but on cleanroom credentials, batch-level traceability, and multi-market regulatory standing that together determine long-term supply reliability. As an Intermittent Catheter Manufacturer producing more than 20 million hydrophilic catheters per year from a 6,000+ m^2 ISO 13485:2016-certified facility in Chengdu, China, Chengdu Daxan Innovative Medical Tech Co., Ltd. (DAXAN) presents a comprehensive overview of its manufacturing infrastructure, product range, regulatory compliance portfolio, and OEM/ODM services designed for urology distributors, importers, and private-label partners worldwide.

ISO 13485 Cleanroom: DAXAN's Verified Production Environment

DAXAN's production base in Chengdu spans more than 6,000 m^2 of cleanroom space and an integrated testing center, all operating under a full ISO 13485:2016 quality management system. ISO 13485:2016 is not simply a cleanliness benchmark — it is the auditable QMS framework that simultaneously underpins DAXAN's CE MDR, FDA 510(k), and NMPA regulatory clearances. Every batch of catheters produced within this facility carries traceability to a documented production environment, giving importers and distributors records they can table in regulatory submissions, market authorization renewals, or supplier due diligence assessments without depending solely on manufacturer-issued assurances.

Within the cleanroom, DAXAN's integrated testing center performs coating performance validation, material safety verification, and dimensional specification checks before products are released for shipment. The proprietary Coatapex™ Hydrolyx™ hydrophilic coating's coefficient of friction — confirmed at COF ≤ 0.02 — is verified batch by batch internally, rather than through periodic external laboratory sampling. This closed-loop verification system enables DAXAN to provide importers with traceable batch inspection records, accelerating supplier qualification timelines and sustaining ongoing

quality assurance requirements under CE MDR and FDA-registered distribution partnerships.

20M Annual Capacity: Supply Scale for Global Urology Distributors

DAXAN's annual production capacity exceeds 20 million hydrophilic intermittent catheters, sustained under ISO 13485 cleanroom conditions since the company's founding in 2016. DAXAN's production is supported by patented automated coating technology (Patent No. ZL201610859829.6), ensuring consistent quality across every catheter. For distributors managing multi-region inventory programs, simultaneous tender commitments, or peak-demand procurement cycles, this figure represents a verifiable supply commitment backed by nine-plus years of continuous manufacturing operations and an active export network spanning 25+ countries. The production scale positions DAXAN to fulfill large-volume orders across multiple distributor accounts while maintaining the batch consistency required under regulated-market supply agreements.

DAXAN intermittent catheters are packaged at 30 units per box and 300 units per carton across its primary product lines, including the Duro-Pocket® RTU and pre-lubricated Nelaton series. Standardized packaging formats support accurate demand forecasting and reduce handling complexity across high-volume procurement cycles.

Intermittent Catheter Range for Urology Care: 9 SKUs and Coatapex™ Hydrolyx™ Hydrophilic Coating Platform

DAXAN's intermittent catheter portfolio comprises 9 SKUs spanning four catheter tip configurations — Nelaton straight tip, Tiemann curved tip, flexible ball tip, and Duro-Pocket® closed system — with FR sizes from CH06 to CH24. Six independent size configurations address the full clinical range of intermittent catheterization needs:

- Pediatric Female: 6–14FR / 20 cm
- Pediatric Male: 6–14FR / 30 cm
- Adult Female: 8–24FR / 20 cm
- Adult Male (Nelaton): 8–24FR / 40 cm
- Adult Male (Tiemann): 6–24FR / 40 cm
- Flexible Tip: 10–16FR / 40 cm

Distributors serving patient populations that include spinal cord injury (SCI), neurogenic bladder, BPH-related urinary retention, and pediatric bladder management can source their complete intermittent catheter catalog from this single China intermittent catheter manufacturer, eliminating multi-supplier coordination and the compliance reconciliation it introduces.

Coatapex™ Hydrolyx™ is DAXAN's proprietary PVP (polyvinylpyrrolidone)-based hydrophilic coating, achieving a coefficient of friction as low as 0.02 and maintaining stable superlubricity for more than 24 hours following activation. For patients managing SCI or neurogenic bladder dysfunction who self-catheterize regularly, this performance level directly supports insertion comfort and mucosal health. All DAXAN catheter materials are produced without natural latex rubber, DEHP, DNIP, or BPA, satisfying allergen sensitivity protocols and material safety requirements across European and North American regulated markets.

The Duro-Pocket® product line is DAXAN's closed-system intermittent catheter family, designed to address infection control requirements at the device level. The RTU (Ready-to-Use) variant is built around a fully enclosed no-touch introducer tip that preserves catheter sterility throughout the insertion

process, paired with fire-polished eyelets that minimize mucosal friction and reduce the risk of tissue damage and associated infection. A 1,300 mL integrated urine collection bag eliminates the need for separate drainage accessories, and the product arrives prehydrated with no preparation required before use. The Duro-Pocket® Water Sachet variant extends the closed-system range with sterile saline 60-second activation, four tip configurations (straight, ball, soft, and Tiemann), and a choice of PVC or TPU, providing configuration flexibility for distributors serving diverse clinical settings.

Regulatory Compliance: CE MDR 2017/745, FDA 510(k), and NMPA

DAXAN's intermittent catheters hold CE Marking under EU MDR 2017/745 (Full Quality Assurance pathway) and two independent FDA 510(k) clearances: K212567 (hydrophilic intermittent catheter) and K243175 (TPU intermittent catheter). DAXAN additionally holds FDA Establishment Registration FEI 3023329815. Both K-numbers are publicly searchable through the FDA 510(k) database, allowing prospective importers to independently verify clearance status before initiating procurement discussions.

Alongside its EU and US clearances, DAXAN holds China NMPA (formerly CFDA) product registration, a Free Sale Certificate (FSC) covering multi-market use, and a CCPIT Certificate of Origin for importers operating across Asian and international regulatory frameworks. ISO 13485:2016 functions as the unified QMS backbone connecting all three compliance frameworks — EU, US, and China — so importers working across two or three jurisdictions simultaneously receive documentation from one manufacturer, one facility, and one auditable quality system, rather than consolidating records from separate production environments.

OEM/ODM Services and Global Reach: Custom Urology Products for 25+ Countries

DAXAN's OEM/ODM program supports full-specification customization across FR sizes CH06 through CH24, covering multiple catheter lengths, four tip configurations (Nelaton, Tiemann, flexible ball, and soft), PVC or TPU material selection, private label branding, and tailored packaging design. Customization is executed within the same ISO 13485:2016 QMS infrastructure as standard catalog production, so private-label products carry the same batch traceability, testing documentation, and regulatory certification coverage as DAXAN's own-brand IC range. OEM services cover the full intermittent catheter portfolio, supporting both single-category and multi-product private-label programs for distributors worldwide.

DAXAN currently exports to more than 25 countries spanning Europe, North America, and Asia. That export footprint reflects operational maturity across multiple compliance documentation systems, differentiated packaging requirements, and sustained cross-border logistics management accumulated over nine-plus years of production. DAXAN maintains active engagement with European distributor markets through ongoing industry participation, reinforcing its standing as an internationally recognized urology catheter manufacturer.

About Chengdu Daxan Innovative Medical Tech Co., Ltd.

Founded in 2016 and headquartered in Chengdu, China, DAXAN is a vertically integrated manufacturer of hydrophilic-coated intermittent catheters and urology care consumables. Its product portfolio spans five categories — intermittent catheters (9 SKUs), Foley catheters, DJ ureteral stents, ureteral access sheaths, and urology guidewires — all produced from a 6,000+ m^2 ISO 13485:2016-certified cleanroom and integrated testing facility. Over nine years of dedicated R&D and manufacturing experience, combined with CE MDR 2017/745, dual FDA 510(k) clearances (K212567 and K243175), and China

NMPA registration, position Chengdu Daxan Innovative Medical Tech Co., Ltd. as a multi-certified, full-range urology device manufacturer with an established export presence across 25+ countries.

Distributors, importers, and OEM/ODM partners seeking product specifications, regulatory documentation, or customization service proposals are invited to contact Chengdu Daxan Innovative Medical Tech Co., Ltd. directly at https://www.daxanmedical.com/

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