China Top Hydrophilic Intermittent Catheter: DAXAN's Advanced Coating Platform for OEM Buyers

Chengdu, Sichuan Jul 24, 2026 (Issuewire.com**)** - For procurement teams and brand partners evaluating intermittent catheter OEM suppliers, the selection threshold has shifted. Where specifications once centered on FR size coverage and baseline CE marking, today's distributor evaluation hinges on something harder to replicate: quantified coating performance, multi-market regulatory clearance, and a manufacturing base capable of sustaining private-label programs at scale. China Top Hydrophilic Intermittent Catheter Factory, Chengdu Daxan Innovative Medical Tech Co., Ltd. (DAXAN), is positioned at that intersection — a hydrophilic intermittent catheter manufacturer with a proprietary five-function coating platform, triple-market regulatory access, and an ISO 13485:2016-certified cleanroom producing over 20 million catheters per year for buyers across more than 25 countries.

DAXAN Advances Its Hydrophilic Intermittent Catheter Coating Platform to Meet Rising Global OEM Demand

Hydrophilic intermittent catheters have become one of the most specification-sensitive product lines in

the urology consumable market. For distributors serving hospital procurement systems and home-care programs, the real cost of a poorly specified OEM supplier is not an initial price difference — it is a delayed market registration, a failed quality audit, or a product recall that removes an entire private-label line from an approved-vendor list. The sourcing standard has shifted accordingly: distributors now look for documented coating performance, triple-market regulatory clearance, and proven cleanroom output capacity.

DAXAN has been building toward that standard since its founding in 2016. Over nine years of R&D and hydrophilic coating production at its Chengdu Medical City facility, the company developed an advanced coating platform — a vertically integrated manufacturing position where coating chemistry, production scale, and multi-market regulatory documentation are managed under one quality system. Products are exported to more than 25 countries spanning North America, Europe, the Middle East, Southeast Asia, and Latin America.

Five Functional Properties of the Coatapex™ Hydrolyx™ Hydrophilic Coating Platform: The Coating Architecture Behind China's Top Hydrophilic Intermittent CatheterPatent-Backed Coating Technology

The Coatapex™ Hydrolyx™ hydrophilic coating platform is supported by patents covering hydrophilic coating preparation (Patent No. ZL201610861058.4), activation-free super-lubricious coating technology (Patent No. ZL201811203221.3), and a hydrophilic-hydrophobic balanced polymer architecture (Patent No. ZL202210283147.0). DAXAN's coating research also includes biomimetic polymer technology (Patent No. ZL201410338238.5).

The Coatapex™ Hydrolyx™ coating platform is not a single-function surface treatment. It is an integrated architecture built on five independent functional dimensions, each addressing a distinct clinical and regulatory concern for OEM buyers sourcing hydrophilic intermittent catheter product lines:

- Super-hydrophilic activation: rapid, uniform water uptake across the catheter surface upon contact with saline or water, ensuring full coating engagement before insertion
- Lubricity: sustained friction reduction to a documentable coefficient of friction value, directly relevant to clinical insertion comfort and mucosal protection
- Antimicrobial properties (Patent No. ZL202110292008.X): antimicrobial surface designed to reduce bacterial adhesion, targeting a primary pathway in catheter-associated urinary tract infections
- Anti-encrustation: surface designed to resist encrustation during the intended single-use window
- Anti-thrombogenic function (Patent No. ZL202310512495.5): surface designed to reduce thrombogenic potential for applications involving mucosal or vascular proximity

For OEM buyers, this architecture changes the sourcing calculus: a five-function platform housed in a single manufacturer means differentiated product lines can be developed, registered, and private-labeled within one quality and regulatory framework, without fragmenting the supply chain across multiple vendors with separate audit tracks.

COF ≤ 0.02 and Stable Superlubricity Exceeding 24 Hours: Quantified Coating Performance Data for OEM Evaluation

For regulatory submissions and clinical evaluations, two coating parameters carry the most weight: the coefficient of friction (COF) and lubricity duration. Together, they define what "hydrophilic" actually means at the point of patient use.

The Coatapex™ Hydrolyx™ coating, formulated on a chemically modified polyvinylpyrrolidone (PVP) base, achieves a COF as low as 0.02 and maintains stable superlubricity for more than 24 hours after water activation. A COF of 0.02 means the coated surface generates minimal frictional resistance against urethral tissue during insertion — a quantitative property that regulatory affairs managers can reference directly in CE MDR technical dossiers or FDA 510(k) submissions.

The 24-hour lubricity duration addresses a less-discussed risk in catheter OEM sourcing: coating degradation before or during use. A coating that loses lubricity rapidly elevates both patient discomfort and infection risk — concerns that register on the distributor's quality record, not just the manufacturer's. The Coatapex™ Hydrolyx™ platform's documented stability window removes that variable from the OEM buyer's risk register.

Full OEM Range Across Nine Catheter Sub-Lines: CH06–CH24 FR, Four Tip Types, and PVC or Medical-Grade TPU

DAXAN's OEM scope covers the complete intermittent catheter product spectrum. Nine IC sub-line SKUs are available for private-label programs, structured around four configurable variables:

- FR sizing: CH06 to CH24, covering pediatric female, pediatric male, adult female, adult male Nelaton, adult male Tiemann, and flexible tip configurations
- Tip types: Nelaton straight, Tiemann angled, flexible ball-shaped, and the Duro-Pocket® enclosed closed-system introducer
- Materials: PVC or DEHP-free, BPA-free medical-grade TPU — with no natural latex rubber in either material option
- Packaging: 30 units per box, 300 units per carton; individual sterile aluminum foil pouches; private-label design and custom packaging on request

This range means a distributor can consolidate its entire hydrophilic intermittent catheter program — from pediatric to adult, from standard to closed-system — under a single OEM agreement with one manufacturer, one quality audit, and one regulatory documentation track.

CE MDR 2017/745, Dual FDA 510(k) Clearances, and ISO 13485:2016: Triple-Market Regulatory Access for Global OEM Partners

Regulatory documentation is the single most time-sensitive variable in catheter OEM procurement. An importer's market registration moves only as fast as the manufacturer's existing clearance package allows. A supplier with documentation gaps in the target jurisdiction does not slow a product launch — it stops it.

DAXAN holds regulatory clearances across three market jurisdictions: CE Marking under EU MDR 2017/745 (Full Quality Assurance pathway), FDA 510(k) clearance K212567 covering hydrophilic intermittent catheters, and FDA 510(k) clearance K243175 covering the TPU intermittent catheter line. The company's FDA Establishment Registration — FEI 3023329815 — is publicly verifiable in the FDA 510(k) database. China NMPA registration and a Free Sale Certificate are held alongside a CCPIT Certificate of Origin, providing the documentation stack that international trade compliance officers typically require at import.

The ISO 13485:2016-certified quality management system provides the foundational audit trail underpinning all three market clearances. For OEM buyers targeting simultaneous entry into EU, US, and Asia-Pacific markets, DAXAN's triple-market documentation package consolidates regulatory risk

into a single, auditable source.

About Chengdu Daxan Innovative Medical Tech Co., Ltd.: 20M+ Hydrophilic Catheters per Year from an ISO 13485-Certified Cleanroom

Chengdu Daxan Innovative Medical Tech Co., Ltd. (DAXAN) was established in 2016 and is headquartered in Chengdu Cross-Strait Science and Technology Industry Development Park, Wenjiang District, Chengdu, Sichuan, China. The company operates a 6,000-square-meter ISO 13485:2016-certified cleanroom with an integrated testing center and annual production capacity exceeding 20 million hydrophilic-coated catheters. Products are exported to more than 25 countries across North America, Europe, the Middle East, Southeast Asia, and Latin America.

DAXAN's urology product portfolio extends beyond intermittent catheters to include silicone and latex Foley catheters, DJ ureteral stents, ureteral access sheaths, and urology guidewires — all manufactured within the same ISO 13485:2016 quality environment. Comprehensive OEM and ODM services, including custom design, private labeling, and tailored packaging, are available across the full product range. With over nine years of R&D expertise, the company is committed to delivering high-quality, cost-effective urology solutions for patients and distribution partners worldwide.

Distributors, importers, and OEM brand owners evaluating DAXAN's hydrophilic intermittent catheter product lines — from the Coatapex™ Hydrolyx™ Nelaton range to the Duro-Pocket® closed-system series — are invited to request product specifications, regulatory documentation packages, and sample inquiries at www.daxanmedical.com.

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