High Quality Hydrophilic Catheter from DAXAN with CE MDR and FDA 510(k) Cleared Urology Care

Chengdu, Sichuan Jul 24, 2026 (Issuewire.com**)** - For procurement teams and medical device importers evaluating urological catheter suppliers, two factors consistently top the source-qualification checklist: verifiable regulatory clearance for the target market, and measurable product performance data that stands independently. Chengdu Daxan Innovative Medical Tech Co., Ltd. (DAXAN) addresses both. The company operates as a dedicated Hydrophilic Catheter Manufacturer based in Chengdu, Sichuan, China — producing hydrophilic-coated intermittent catheters with a coefficient of friction (COF) as low as 0.02 under the proprietary Coatapex™ Hydrolyx™ hydrophilic coating platform and holding CE certification under EU MDR 2017/745 alongside two independent US FDA 510(k) clearances: K212567 and K243175. Products reach distributors in more than 25 countries, supported by a compliance architecture that covers EU, US, and Asia-Pacific market access from a single manufacturing source.

DAXAN Announces High-Quality Hydrophilic Catheter Line with CE MDR and Dual FDA 510(k) Clearance

Chengdu Daxan Innovative Medical Tech Co., Ltd. has announced its high-quality hydrophilic catheter line to the global urology device market — a product range that arrives with dual-market regulatory clearance already documented. The CE marking under EU MDR 2017/745 was granted via the Full Quality Assurance route, a certification pathway that requires third-party notified body review of the entire quality management system rather than individual product submissions. On the US side, FDA 510(k) clearance K212567 covers the hydrophilic intermittent catheter, and K243175 covers the TPU intermittent catheter — two distinct clearances for two core material lines. FDA Establishment Registration FEI 3023329815 is on record and independently verifiable through the FDA database.

For distributors and importers consolidating EU and US sourcing with one hydrophilic catheter manufacturer, this combination removes the need to qualify two separate suppliers for two regulatory zones. The catheter range covers CH06 to CH24 in Nelaton, Tiemann, flexible ball-tip, and Duro-Pocket® closed-system configurations, accommodating pediatric through adult female and male patient populations. China NMPA registration, a Free Sale Certificate (FSC), and a Certificate of Origin issued by the China Council for the Promotion of International Trade (CCPIT) extend the documentation package for buyers operating in Asia-Pacific and emerging markets simultaneously.

Coatapex™ Hydrolyx™ Proprietary Hydrophilic Coating Achieves COF ≤ 0.02 and Stable Lubricity Beyond 24 Hours

Coatapex™ Hydrolyx™ is DAXAN's proprietary hydrophilic coating brand, formulated on a chemically modified PVP (polyvinylpyrrolidone) base. Once activated, the coating achieves a coefficient of friction as low as 0.02 — a quantified engineering figure that can be cited directly in product technical dossiers, procurement specifications, or comparative evaluations. Stable superlubricity is maintained beyond 24-hour post-activation, addressing the performance durability question that catheter importers most frequently raise when comparing coating platforms from different suppliers. The platform is supported by DAXAN patents covering a hydrophilic super-lubricious coating preparation method (Patent No. ZL201610861058.4) and a water-based hydrophilic lubricious coating (Patent No. ZL201810063901.3).

The Coatapex™ Hydrolyx™ coating combines super-hydrophilic surface activation, low-friction delivery, antimicrobial protection, anti-encrustation resistance, and anti-thrombogenic properties within a single platform.

CE MDR 2017/745 Full Quality Assurance Certification Confirms European Compliance

EU MDR 2017/745 replaced the Medical Device Directive in 2021, applying rigorous design control, clinical evaluation, and post-market surveillance requirements to all device manufacturers serving European markets. DAXAN's CE certification was obtained via the Full Quality Assurance route — a pathway that subjects the entire quality management system to audit by a designated notified body. Coverage extends to all manufacturing processes, not only documentation filed for a specific product model or lot. Full Quality Assurance is system-level compliance: a more comprehensive regulatory status than a product-specific filing.

ISO 13485:2016 quality management system certification provides the auditable backbone against which CE MDR compliance is maintained. For European importers and regional distributors, the combination of ISO 13485:2016 and CE MDR Full Quality Assurance represents a documented, system-level compliance record built to withstand procurement audits.

Dual FDA 510(k) Clearances K212567 and K243175 Support US Market Access for Hydrophilic Catheters

DAXAN holds two independent FDA 510(k) clearances: K212567 for the hydrophilic intermittent catheter and K243175 for the TPU intermittent catheter. The two clearances correspond to two distinct material lines within the product range. US distributors sourcing standard hydrophilic PVC/TPU catheters reference K212567; those sourcing the body-conforming TPU variant reference K243175. Both K-numbers are verifiable through the FDA 510(k) database, providing independent third-party confirmation outside the manufacturer's own records.

FDA Establishment Registration FEI 3023329815 completes the US compliance file, confirming the manufacturing site's registration status in the FDA's public database. For distributors preparing hospital formulary submissions, competitive tender documentation, or standard import filings, the dual clearances and establishment registration provide a layered, auditable document chain.

DEHP-Free, BPA-Free Medical-Grade TPU and Latex-Free Construction Prioritize Patient Safety

DAXAN's hydrophilic catheters are manufactured from medical-grade thermoplastic polyurethane (TPU). The material construction explicitly excludes natural rubber latex, DEHP and DNIP plasticizers, and BPA; the same TPU formulation is biodegradable in natural settings. Latex-free, DEHP-free, and BPA-free declarations are standard requirements in EU and US import documentation packages, distributor labeling compliance reviews, and hospital tender specifications. Documenting all three on the product record reduces the verification steps procurement teams must complete independently.

Hot-polished side eyelets are applied to catheter tubing as a standard manufacturing process. Polishing removes rough edges from the drainage openings, reducing mechanical contact with urethral mucosa during insertion and withdrawal. The catheter range covers sizes FR 8 through FR 24 across pediatric female, pediatric male, adult female, and adult male configurations, with a pre-lubricated ready-to-use (RTU) design that requires no additional water sachet preparation.

ISO 13485:2016 Certified Cleanroom Facility and 20M Annual Capacity Back Consistent Global Supply

DAXAN operates a cleanroom production facility exceeding 6,000 square meters, incorporating an integrated testing center on the same site. The facility runs under ISO 13485:2016 certification and encompasses advanced manufacturing processes — extrusion molding, injection molding, punching, and complete packaging — within a vertically controlled environment.

Annual production capacity exceeds 20 million hydrophilic-coated catheters — a scale that supports large regional distributors managing standing orders and long-term supply agreements. Chengdu Daxan Innovative Medical Tech Co., Ltd. was established in 2016, accumulating 9+ years of R&D and production experience in the hydrophilic intermittent catheter segment. Products are currently exported to more than 25 countries across North America, Europe, the Middle East, Southeast Asia, and Latin America.

About DAXAN — Chengdu Daxan Innovative Medical Tech Co., Ltd.

DAXAN — Chengdu Daxan Innovative Medical Tech Co., Ltd. — is a specialized hydrophilic catheter manufacturer established in 2016 and headquartered at No. 566 Kexing Road West Section, Chengdu Cross-Strait Science and Technology Industry Development Park, Wenjiang District, Chengdu, Sichuan, China. The company's product portfolio covers five core urology categories: intermittent catheters (9 SKUs, including Nelaton, Tiemann, flexible-tip, and Duro-Pocket® closed-system configurations), Foley catheters, DJ ureteral stents, ureteral access sheaths, and urology guidewires. Certifications held include ISO 13485:2016, CE MDR 2017/745 (Full Quality Assurance), FDA 510(k)

K212567 and K243175, FDA Establishment Registration FEI 3023329815, China NMPA registration, Free Sale Certificate (FSC), and CCPIT Certificate of Origin. OEM and ODM services cover FR sizes CH06 to CH24, with four tip options, PVC or TPU material selection, and private-label packaging.

Importers, distributors, and OEM partners seeking product specifications, regulatory documentation, and customization details are invited to visit https://www.daxanmedical.com/

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