

Custom DuroFlex™ Catheter by DAXAN with Super-Hydrophilic Coating Technology and OEM Support



Chengdu, Sichuan Jul 24, 2026 ([Issuewire.com](https://www.issuewire.com)) - Male intermittent self-catheterization (ISC) presents a specific anatomical challenge. The natural curvature of the male urethra demands a catheter tip that can navigate its bends while reducing mucosal friction and insertion resistance compared to standard straight-tipped designs. For distributors and procurement teams assessing a [DuroFlex™ Catheter Manufacturer](#), the central question is whether a product was genuinely engineered for male anatomy — or adapted from a unisex design and marketed as a fit.

Chengdu Daxan Innovative Medical Tech Co., Ltd. (DAXAN), an ISO 13485:2016-certified manufacturer of hydrophilic-coated intermittent catheters, has developed the DuroFlex™ pre-lubricated flexible tip ISC catheter to address this need directly. The product integrates a flexible ball-shaped tip designed for the contours of the male urethra with DAXAN's Coatapex™ Hydrolyx™ super-hydrophilic coating technology, supported by Patent No. ZL201610861058.4 and built on a PVP-based formulation that delivers a coefficient of friction (COF) as low as 0.02 with stable lubricity maintained for more than 24 hours. CE MDR 2017/745, FDA 510(k) clearance, and China NMPA registration back the product on

three regulatory tracks simultaneously, with OEM customization available across a broad range of French sizes.

Intermittent catheter procurement has increasingly shifted from product-level comparison to manufacturer-level assessment: coating performance data, cleanroom certification, multi-market regulatory documentation, and OEM service scope now drive distributor selection. On each of these dimensions, Chengdu Daxan Innovative Medical Tech Co., Ltd. has built the DuroFlex™ to provide verifiable answers.

DuroFlex™ Flexible Ball Tip: Engineered for Male Urethral Anatomy

The defining design decision behind the DuroFlex™ is its flexible ball-shaped tip, developed specifically for the anatomical contours of the male urethra. Unlike rigid straight-tipped alternatives, the ball-shaped tip adapts to natural curves and directional changes during insertion, reducing both catheter resistance and the risk of mucosal trauma at contact points. For male patients who perform intermittent catheterization multiple times daily — including those managing neurogenic bladder dysfunction, spinal cord injury, benign prostatic hyperplasia (BPH), or urethral stricture — repeated micro-traumas accumulate into clinically meaningful infection and tissue-damage risk. Tip geometry is not a secondary comfort feature; it is a primary engineering decision.

The DuroFlex™ is available in four French sizes — 10FR, 12FR, 14FR, and 16FR — all at a 40 cm catheter length. Each catheter is supplied in an individual aluminum foil sealed pouch, packed 30 units to a box, with dual tear holes and an adhesive hanging sticker. A non-touch gripper sleeve supports aseptic handling throughout the insertion procedure, while hot-polished smooth eyelets on the tube body minimize urethral irritation during insertion and withdrawal. Every unit is sterile, single-use, and sealed at the point of manufacture, eliminating preparation steps at the point of care. Full product specifications are available on the Pre-Lubricated Flexible Tip ISC Catheter for Men product page.

Super-Hydrophilic Coating Technology: Coatapex™ Hydrolyx™ Five-Function Platform

The DuroFlex™ carries DAXAN's proprietary Coatapex™ Hydrolyx™ hydrophilic coating — a PVP-based formulation that achieves a coefficient of friction as low as 0.02 and maintains stable superlubricity for more than 24 hours after activation. These are measurable performance parameters against which procurement evaluators can benchmark the coating during supplier qualification — not marketing language. The coating technology is also supported by Patent Nos. ZL201811203221.3 and ZL202210283147.0.

The Coatapex™ Hydrolyx™ platform is structured around five functional properties: super-hydrophilic surface activation, lubricious friction management, antimicrobial properties (Patent No. ZL202110292008.X) - a surface designed to reduce bacterial adhesion, anti-encrustation - a surface designed to resist encrustation, and anti-thrombogenic function (Patent No. ZL202310512495.5) - a surface designed to reduce thrombogenic potential. Together, these functions address catheter-associated risks that extend well beyond the insertion event: encrustation buildup that can degrade performance over repeated catheterization cycles, and thrombogenic surface interactions relevant to extended-use contexts. For high-frequency ISC users — individuals who may self-catheterize four to six times daily — the combination of a $\text{COF} \leq 0.02$ surface and sustained lubricity past 24 hours means the coating performs consistently from first use to last within each catheterization day. The Coatapex™ Hydrolyx™ coating is applied across DAXAN's Hydrophilic Nelaton Straight Catheter range as well, making it a platform-level differentiator across the manufacturer's intermittent catheter portfolio.

Medical-Grade TPU and Hygienic Single-Use Packaging: Material Safety Standards for Global Compliance

The DuroFlex™ catheter body is manufactured from medical-grade TPU — a thermoplastic elastomer that softens at body temperature to conform naturally to the urethral pathway, while satisfying a material safety profile that international procurement audits routinely require. The material is DEHP-free, BPA-free, and free of natural latex rubber, eliminating three of the most commonly flagged allergen and plasticizer concerns in urology catheter procurement across EU, US, and Asia-Pacific regulated markets. The TPU formulation also biodegrades safely in natural environments — a material property aligned with distributor-level sustainability requirements increasingly common in European market procurement.

The single-use, sterile presentation removes reprocessing risk entirely, supporting both clinical and home-use storage contexts and giving distributors a patient-safety and compliance advantage that is directly verifiable at the importer qualification stage.

ISO 13485 Manufacturing Infrastructure and Triple-Market Regulatory Compliance

The DuroFlex™ is manufactured in [DAXAN](#)'s 6,000+ m² ISO 13485:2016-certified cleanroom facility in Chengdu, Sichuan — a production environment integrating advanced extrusion, molding, punching, and packaging technologies alongside an in-house testing center. Annual production capacity exceeds 20 million hydrophilic-coated catheters, providing the supply volume that makes framework agreements and large-volume distributor programs viable without capacity risk. DAXAN's coating output is also supported by its patented automated coating device and process (Patent No. ZL201610859829.6).

On the regulatory side, Chengdu Daxan Innovative Medical Tech Co., Ltd. holds CE marking under EU MDR 2017/745 (Full Quality Assurance route), FDA 510(k) clearances K212567 and K243175, and China NMPA registration — a triple-market compliance profile that positions the manufacturer as a verifiable sourcing origin for import documentation across Europe, North America, and China simultaneously. The FDA Establishment Registration number FEI 3023329815 is publicly verifiable on the US FDA database. Export compliance documentation includes a Free Sale Certificate and a Certificate of Origin issued by CCPIT. Founded in 2016, the company has accumulated more than 9 years of hydrophilic catheter R&D and production experience, with products distributed to more than 25 countries across North America, Europe, the Middle East, Southeast Asia, and Latin America.

Flexible OEM and Private-Label Programs: Full CH06–CH24 Customization for Global Distributors

For distributors and brand owners seeking private-label intermittent catheters for specific market segments, Chengdu Daxan Innovative Medical Tech Co., Ltd. offers OEM and ODM programs spanning the full CH06–CH24 French size range, multiple catheter lengths, four tip configurations (straight, ball-shaped, soft, and Tiemann), and a choice of PVC or TPU tubing material. Private labeling, custom packaging design, and tailored product specifications are supported across the DuroFlex™ line and DAXAN's broader intermittent catheter portfolio.

A single manufacturing partner can therefore serve differentiated SKU requirements across market segments without splitting the supply chain: a pediatric straight-tip program for a European distributor, an adult male flexible-tip line for a North American brand, a Tiemann-tip series for a Middle Eastern importer. The customization scope — specific FR sizes, catheter lengths, tip geometry, and material choice — is published directly on product pages and available for verification during supplier qualification. For full customization details, visit the [DAXAN intermittent catheter category page](#).

From a flexible tip engineered for male anatomy to a patented coating platform, ISO-certified manufacturing, and full OEM customization, the DuroFlex™ gives global urology distributors and importers a complete, auditable answer to source with confidence. For product specifications, OEM program details, and regulatory documentation, visit DAXAN's official website or contact the team through the inquiry page at <https://www.daxanmedical.com/>



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Source : Chengdu Daxan Innovative Medical Tech Co., Ltd.

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