

China Leading Medical Catheter OEM Supplier DAXAN: CE MDR, FDA 510(k), and NMPA Registration for Importers



Chengdu, Sichuan Jul 24, 2026 ([Issuewire.com](https://www.issuewire.com)) - Selecting a reliable [Medical Catheter OEM Supplier](#) from China involves more than evaluating unit cost and production capacity. For international importers, the deciding criterion is regulatory coverage: does a single manufacturer hold the compliance stack — EU MDR 2017/745, US FDA 510(k), and China NMPA — that satisfies each target market's qualification threshold? Very few China-based catheter manufacturers can answer yes to all three.

DAXAN — the commercial brand of Chengdu Daxan Innovative Medical Tech Co., Ltd., established in Chengdu in 2016 — has built precisely that regulatory architecture. Operating from a 6,000 m² ISO 13485:2016-certified cleanroom with an integrated testing center, the company produces more than 20 million hydrophilic catheters annually and exports to more than 25 countries, serving distributors, brand owners, and OEM partners across Europe, North America, and the Asia-Pacific region.

This press release outlines the three-tier regulatory framework DAXAN has established as a medical catheter OEM supplier, the manufacturing foundation that supports it, and the OEM customization

scope available to international importers.

DAXAN Confirms Triple Regulatory Certification as a Medical Catheter OEM Supplier for International Importers

Chengdu Daxan Innovative Medical Tech Co., Ltd. has confirmed simultaneous certification across three independent regulatory frameworks: CE Marking under EU MDR 2017/745 (Full Quality Assurance pathway), FDA 510(k) clearances K212567 and K243175, and China NMPA (formerly CFDA) registration — all underpinned by an ISO 13485:2016 quality management system. Combined with FDA Establishment Registration FEI 3023329815, this compliance portfolio places DAXAN among a small group of China-based urology manufacturers that can support importer qualification for the EU, US, and Chinese domestic markets from a single source.

International importers evaluating a medical catheter OEM supplier typically open their assessment at the certificate level: EU buyers verify CE MDR compliance and the specific Notified Body pathway; US buyers request 510(k) K-numbers and facility registration; Asia-Pacific procurement teams confirm NMPA status and export documentation.

CE MDR 2017/745 Compliance: Full Quality Assurance Pathway for European Medical Catheter Importers

DAXAN holds CE Marking under EU MDR 2017/745 via the Full Quality Assurance pathway — the route that subjects the manufacturer's complete design development and production quality system to Notified Body oversight, rather than one-time product-type examination only. Intermittent catheters are classified as Class IIa medical devices under MDR 2017/745, and EU and EEA importers cannot place them on the European market without a valid CE mark issued under the updated regulation.

For EU importers who have revised supply chains since the MDR transition, the Full Quality Assurance route signals a higher level of manufacturer engagement with European regulatory requirements. Design controls, batch production records, post-market surveillance reporting, and the technical documentation package are all reviewed and monitored by the certifying Notified Body — not assessed once and left static.

DAXAN's CE MDR certification covers its hydrophilic-coated intermittent catheter product lines. The underlying ISO 13485:2016 quality system aligns the technical documentation architecture with the structure EU importers expect to submit during national competent authority registration.

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

DAXAN holds two independent FDA 510(k) clearances: K212567, covering its hydrophilic-coated intermittent catheter line, and K243175, covering its TPU intermittent catheter series. Both K-numbers are publicly searchable in the FDA 510(k) database, giving US importers independently verifiable product-level market-access documentation at the point of supplier evaluation.

The dual-clearance structure reflects DAXAN's two primary material lines. US distributors sourcing standard hydrophilic PVC catheters reference K212567; those sourcing the body-conforming TPU variant reference K243175.

Alongside product clearances, DAXAN holds FDA Establishment Registration FEI 3023329815,

searchable via the FDA's online facility registry. Product-level 510(k) clearance paired with facility-level FDA registration constitutes the dual-layer documentation structure that US importers' regulatory affairs teams typically require before completing supplier qualification.

NMPA Registration and Export Documentation: China Compliance Credentials for Asian Distribution Partners

China NMPA (formerly CFDA) registration confirms that DAXAN's catheter products have satisfied domestic regulatory review under China's medical device framework — covering product standards conformity, quality system assessment, and post-market monitoring requirements. For Asia-Pacific importers whose local registration processes reference the manufacturing country's regulatory status, NMPA registration provides a recognized compliance signal from source.

DAXAN also holds a Free Sale Certificate (FSC) and a CCPIT Certificate of Origin. The FSC documents export eligibility for markets outside the EU and US regulatory frameworks — frequently required by importers in Southeast Asia, the Middle East, and Latin America when filing market entry or product registration applications. The CCPIT Certificate of Origin serves customs and tariff documentation functions in cross-border trade, confirming Chinese origin for duty assessment and distribution agreement compliance.

Together, NMPA registration, FSC, and the CCPIT origin certificate give distribution partners across emerging markets a complete, single-source documentation package: product compliance from the manufacturing country, export legitimacy, and origin verification.

ISO 13485:2016 Cleanroom Facility and 20M Annual Capacity: The Manufacturing Foundation Behind Triple-Market Certification

Every regulatory certification in DAXAN's portfolio rests on the same manufacturing foundation: a 6,000 m² ISO 13485:2016-certified cleanroom in Chengdu, supported by an integrated testing center and producing more than 20 million hydrophilic catheters per year. The ISO 13485:2016 quality management system is not simply a prerequisite credential — it is the structural link that connects all three regulatory frameworks simultaneously.

CE MDR technical documentation, the FDA's Quality System Regulation, and NMPA's audit criteria all treat ISO 13485 as their structural backbone. Because one certified QMS underpins all three registrations, importers aren't reviewing three parallel compliance structures — they're auditing a single documented production environment that satisfies three regulators, a meaningful efficiency gain in supplier qualification.

The 20M+ annual production capacity provides importers with the supply stability required for framework contracts, multi-SKU private label programs, and volume-variable distribution agreements.

OEM Catheter Programs for Importers: FR Sizes CH06–CH24, Four Tip Configurations, and Private Labeling

[DAXAN](#)'s OEM program is structured for importers managing multi-SKU urology catheter portfolios. French size coverage spans CH06 to CH24, with length and tip configurations defined per target market and patient population. Four tip types are available — Nelaton straight, Tiemann coude, ball, and flexible — accommodating clinical requirements across neurogenic bladder, BPH, urethral stricture, and standard self-catheterization indications. Material selection covers medical-grade PVC and DEHP-free,

BPA-free TPU, with private label packaging customizable by brand, language, and distribution unit.

The hydrophilic coating applied across DAXAN's OEM intermittent catheter range is the proprietary Coatapex™ Hydrolyx™ platform — a PVP-based formulation designed for very low surface friction and stable lubricity well after activation. The OEM coating platform is supported by DAXAN Patent Nos. ZL201610861058.4 and ZL201811203221.3.

OEM product families available for private label programs include the hydrophilic Nelaton straight-tip catheter range, the Duro-Pocket® closed-system catheter line in both RTU and water sachet-activated formats, and the DuroFlex™ flexible-tip ISC catheter for male anatomy applications. Each product line is manufactured within DAXAN's ISO 13485 cleanroom and carries the CE MDR, FDA 510(k), and NMPA certifications relevant to its market pathway.

For importers consolidating compliance, supply capacity, and OEM flexibility into a single medical catheter OEM supplier relationship, Chengdu Daxan Innovative Medical Tech Co., Ltd. presents a documented and auditable manufacturing option. Product specifications, regulatory documentation packages, and OEM program details are available directly through www.daxanmedical.com.



Media Contact

Chengdu Daxan Innovative Medical Tech Co., Ltd.

*****@daxanmed.com

<http://www.daxanmedical.com>

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

[See on IssueWire](#)

