



THE OPPORTUNITY



Kentro KTR-2610 TENS product image. Representative electrotherapy device only; not the proposed combination SKU or evidence of Saudi authorisation, treatment efficacy or report prices.

CHINA TO SAUDI ARABIA

A partner-led market. Prove the route. Then test demand.

Understand the buyer, the competition and the economics before committing. Full market analysis, source links and practical next questions.



Go / No-Go.

BEFORE YOU MAKE THE COMMITMENT

GO ONLY WHEN THESE CONDITIONS ARE MET

Commit to a full launch only if, within 90 days, SFDA registration is filed with a written timeline under 6 months, at least one Saudi distributor signs a minimum purchase commitment, and the revised landed cost keeps contribution per unit above SAR 55.

NO-GO: If a required condition is unproven or missed, hold the commitment described above. Resolve it before proceeding.

Registration filing is not product authorisation. Confirm the lawful import and sale route with a qualified Saudi representative.



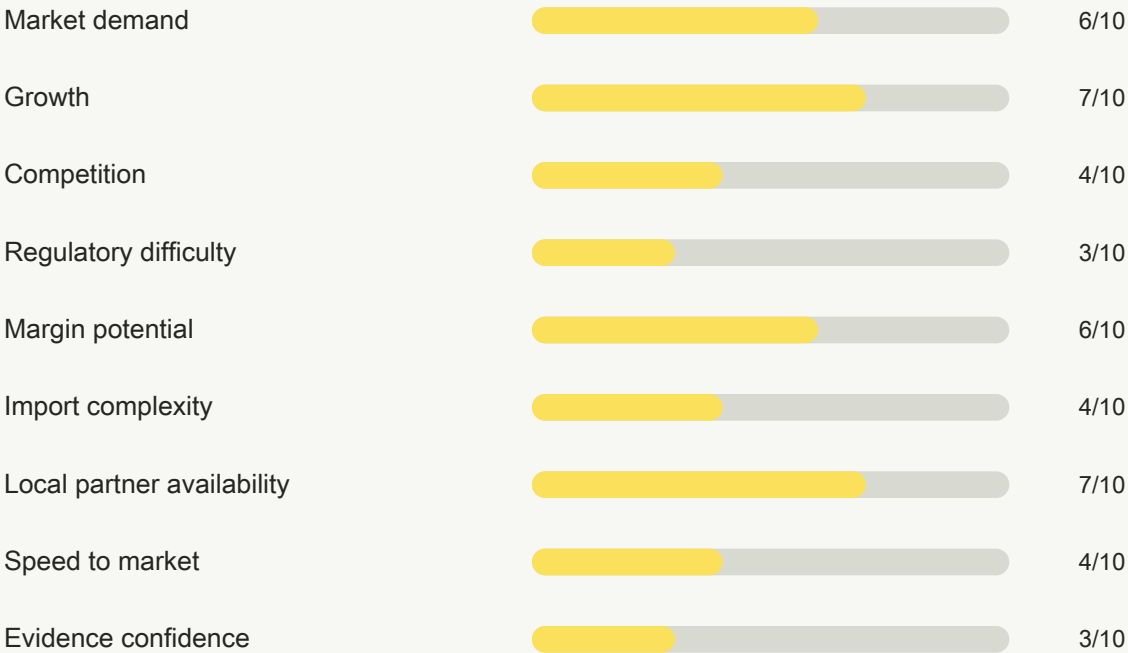
READ THE SIGNALS

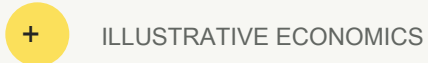
Demand. Competition. Evidence.

The source recommends a controlled pilot.
Scores are judgments based on available public evidence, not guarantees of demand, safety or profitability.



Detailed scorecard. Overview:
7/10. The difference remains
unresolved in the source.





Know the numbers.

Source-report pilot targets. Not manufacturer quotations, actual transaction prices or guaranteed margins.

TARGET RETAIL

SAR 250-450

Estimated planning scenario

TARGET LANDED

SAR 95-140

Estimated planning scenario

DISTRIBUTOR MARGIN

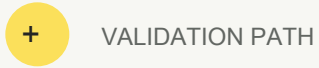
35-50%

Estimated planning scenario

TEST ENTRY BUDGET

SAR 180k-320k

Estimated planning scenario



Three gates. One clear next move.

01

Prove the product

Check the exact configuration, intended user, performance and model-specific safety documents.

02

Prove the cost

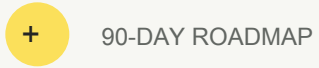
Replace estimated product, freight, duty and testing inputs with written quotations.

03

Prove the demand

Use a paid pilot to measure willingness to pay, sell-through, returns and support costs.

Regulatory, tariff and safety statements in the source have not been independently verified for the exact SKU. Qualified advice and current documents are required before a commitment.

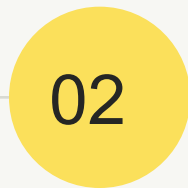


Validate. Build. Measure.



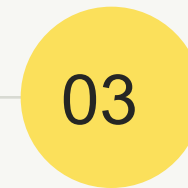
Days 0-30

Confirm exact device classification, qualified Saudi representation and distributor interest.



Days 31-60

Obtain model-specific documents, written regulatory timelines and revised unit economics.



Days 61-90

Review signed purchase interest and contribution gates; do not sell before required authorisation.

A conditional action plan, not a guaranteed 90-day launch. The source gives 4-7 months from purchase order to first sale; authorisation and qualified local representation remain the critical path.



Read the differences before committing.

01

Two scores, low decision confidence

Overview: 7/10. Detailed scorecard: 5/10. The source decision itself is marked low confidence; validate the exact product and channel.

02

The landed figures differ

Decision target: SAR 95-140. Detailed stated base: SAR 144 (SAR 130 excluding VAT). Listed monetary components total SAR 140; obtain actual quotes and reconcile the model.

03

Do not combine margin scenarios

Decision: 35-50% distributor and 55-65% direct-to-clinic. Detailed model: 31% at SAR 210 transfer price and SAR 144 landed cost. Channel and fee bases differ.

04

A filing is not permission to sell

The source trigger requires a registration filing and timeline. Filing alone is not product authorisation. Have a qualified Saudi representative confirm the lawful import and sale route.

Market overview

Saudi Arabia · TENS & EMS Devices

Report date: 7 October 2026.

Opportunity score

7/10 out of 10

Assessment

Solid Market overall



Market overview

Market value and growth

Middle East TENS market estimated at USD 95 million; Saudi Arabia electro-medical electrotherapeutic apparatus market at USD 320 million in 2025 growing 11.75% CAGR for Saudi electrotherapeutic apparatus (2025-2031); 6.5% CAGR for Middle East & Africa TENS devices (2026-2030)

Executive Summary

Saudi Arabia's TENS & EMS opportunity sits inside a fast-growing electrotherapy apparatus market valued at USD 320 million in 2025 and forecast to reach USD 600 million by 2031 at an 11.75% CAGR, with the Middle East TENS segment alone estimated at USD 95 million and led by Saudi Arabia, the UAE and Egypt. Demand is driven by a chronic disease burden affecting over 8 million people, government healthcare infrastructure investment under Vision 2030, and a shift toward home-based, drug-free pain management. Portable digital TENS devices are the leading product type, while limited reimbursement (only about 20% of regional health insurance plans cover TENS) keeps most purchases out-of-pocket and price-sensitive. Entry requires SFDA medical device registration, SABER/Saleem conformity certification and typically a local importer or distributor, with import duties commonly in the 5%-25% band and electronics often at 5%. The strongest play is a competitively priced portable or wearable TENS/EMS unit sold through established Saudi medical device distributors and online retail channels such as Amazon.sa and Noon.

Opportunity assessment - Solid Market Saudi Arabia is one of the three dominant Middle East TENS markets, with double-digit growth in the broader electrotherapy apparatus category and strong structural demand from chronic pain, diabetes and musculoskeletal conditions. The main constraints are weak insurance reimbursement, mandatory SFDA/SABER compliance, and a crowded field of established distributors, which temper the score to a solid rather than hot opportunity.



Decision in 60 Seconds

The figures below are source-report estimates or scenarios, not a quotation from the featured supplier. Confirm assumptions and actual costs before committing.

TEST Saudi demand for drug-free pain management is real and growing, but SFDA medical-device registration, SABER conformity and limited insurance reimbursement make this a small, disciplined test order rather than a full launch.

Best customer

Saudi physiotherapy/rehab clinic chains and home-healthcare providers buying portable dual-channel TENS+EMS units in 50-200 unit lots

Best product

Portable dual-channel digital TENS+EMS combination unit, rechargeable, 12-15 pre-set programs, CE-marked, ISO 13485 manufacturer



Decision in 60 Seconds

Best channel

Appoint one established Riyadh/Jeddah medical-device distributor who already holds SFDA establishment registration and SABER access

Target retail price

SAR 250-450 per unit (online/retail); SAR 180-280 per unit to clinics in bulk

Target landed cost

SAR 95-140 per unit at 500-unit order

Expected gross margin

35-50% at distributor level; 55-65% at direct-to-clinic level

Entry budget

SAR 180,000-320,000 (USD 48,000-85,000) for first 500-unit test including registration, certification and freight

Time to market

4-7 months from PO to first sale (SFDA/SABER registration is the critical path)



Decision in 60 Seconds

Biggest obstacle

SFDA medical-device registration and SABER Certificate of Conformity - without a Saudi importer of record holding the right licences, goods cannot clear customs

Confidence in this call

Low

Opportunity Scorecard

5/10

Overall score

Market demand

Score: 6/10

Why: Chronic pain, diabetes and musculoskeletal disease burden is high and government is expanding healthcare capacity, but TENS is a discretionary adjunct therapy, not a reimbursed essential.

Growth

Score: 7/10

Why: Middle East TENS growth cited at ~6.5% CAGR and Saudi electrotherapeutic apparatus at ~11.75% CAGR to 2031, both above global TENS growth of ~4-7%.

Opportunity Scorecard

Competition

Score: 4/10

Why: Global brands (Omron, Zewa, TruMedic, HealthmateForever) plus cheap Chinese units already sell on Amazon.sa and Noon; no evidence of a dominant local brand, but price competition is severe.

Regulatory difficulty

Score: 3/10

Why: TENS/EMS units are regulated medical devices requiring SFDA registration, ISO 13485-aligned QMS evidence and SABER Certificate of Conformity; process is slow and importer-dependent.

Margin potential

Score: 6/10

Why: Entry-level units retail USD 20-50 globally and wholesale discounts run 20-40%; Saudi retail pricing supports SAR 250-450, leaving workable but not exceptional margin after duty and VAT.

Import complexity

Score: 4/10

Why: 12-digit HS classification, CIF-based duty and VAT, SABER/Saleem portal access restricted to importers and SASO-approved bodies; misclassification causes delays and penalties.

Opportunity Scorecard

Local partner availability

Score: 7/10

Why: Saudi Arabia has a deep bench of medical-device distributors (Al-Ewan, FMS, Balikh, Rose Aljazera, ProMedEx, Lana Medical, Rustom Medical) actively seeking new lines.

Speed to market

Score: 4/10

Why: Registration and conformity certification realistically take 3-6 months before any commercial shipment clears.

Evidence confidence

Score: 3/10

Why: Market sizing comes from commercial research firms with inconsistent figures; no Saudi-specific TENS volume, price or channel data was found, and no tariff line for TENS was confirmed.

A viable niche with real demand and available partners, but the regulatory gate and thin evidence base mean this should be entered as a small, partner-led test, not a scale launch.

A proxy, not a precise market size.



2025 Saudi electrotherapy

11.75%
CAGR



2031 parent-market forecast

The forecast covers Saudi electrotherapeutic apparatus, not TENS/EMS alone. The separate USD 95m Middle East TENS estimate has a different geographic and product scope.

Market Size & Growth

Market value (2025)

Middle East TENS market estimated at USD 95 million; Saudi Arabia electro-medical electrotherapeutic apparatus market at USD 320 million in 2025

Growth rate

11.75% CAGR for Saudi electrotherapeutic apparatus (2025-2031); 6.5% CAGR for Middle East & Africa TENS devices (2026-2030)

Forecast (2031)

USD 600 million for Saudi electrotherapeutic apparatus

Confidence

MEDIUM



Market Size & Growth

Basis

Ken Research estimates for the Middle East TENS market and Saudi electrotherapeutic apparatus market; global TENS figures from Grand View Research, Cognitive Market Research, Verified Market Reports and The Business Research Company vary widely (USD 321.1 million to USD 1.44 billion), so Saudi-specific sizing is an estimate derived from regional shares.

Demand Drivers

1 Chronic disease and pain burden High Over 8 million people in Saudi Arabia are affected by diabetes and cardiovascular diseases, and WHO reports chronic diseases account for 73% of total deaths, driving demand for non-invasive electrotherapeutic pain management.

2 Government healthcare infrastructure investment High Saudi Arabia is building new hospitals, medical centers and specialized facilities, creating clinical adoption opportunities for TENS devices to improve workflow and patient care.

3 Shift to home-based and drug-free pain management High Portable digital TENS devices lead the Middle East market due to convenience, multi-program settings and lower cost versus clinic-based therapy, supporting self-management of chronic pain.

4 Vision 2030 private sector healthcare expansion Medium Vision 2030 reforms aim to raise the private sector's healthcare contribution from 25% to 35%, expanding the number of facilities and distributors handling medical equipment.

Trending Now

1 Portable digital TENS devices Accelerating Portable digital units are the leading Middle East TENS product type, favored for convenience, multi-program settings and mobile health connectivity. Signal: Ken Research identifies portable digital TENS as the leading segment in the Middle East market.

2 Wireless and wearable electrotherapy Accelerating Wearable electrotherapy innovations support uninterrupted pain relief and expand home care adoption globally, with wireless/wearable TENS listed as a distinct Middle East segment. Signal: The Business Research Company cites wearable electrotherapy as a key market trend.

3 Combination TENS & EMS devices Steady Combination TENS and EMS units are tracked as one of four main Middle East product segments, appealing to users wanting both pain relief and muscle stimulation in one device. Signal: Ken Research segments the Middle East market into conventional, portable digital, wireless/wearable and combination TENS & EMS devices.

4 Online retail expansion Accelerating TENS units are widely listed on Amazon.sa and Noon with free shipping, free returns and cash on delivery, lowering the barrier for consumer purchases. Signal: Amazon.sa and Noon both carry extensive TENS device assortments for Saudi customers.



Seasonality

Peak months

August

Planning note

SaleHoo data shows TENS demand typically peaks in August, aligned with back-to-school and workplace safety refresh cycles; MENA retail also shows four seasonal peaks with elevated discount search interest in Saudi Arabia, so inventory and promotions should be planned around these windows.



Consumer Insights

Typical buyer

A mix of individual consumers managing chronic or musculoskeletal pain at home, physiotherapy and rehabilitation clinics, and hospitals procuring through distributors.

Demographics

Skewed toward older adults with chronic pain and musculoskeletal conditions, plus a younger active population purchasing EMS units for muscle stimulation and recovery.

Price sensitivity

High

Sensitivity note

With only about 20% of regional health insurance plans covering TENS devices, most buyers pay out of pocket, making entry-level pricing and online discounts decisive.



Consumer Insights

What they value

Drug-free pain relief, Portability and ease of use, Affordability, Multi-program functionality, Brand trust and certification

Where they buy

Online retail (Amazon.sa, Noon), Medical equipment distributors, Physiotherapy and rehabilitation clinics, Hospitals

Purchase drivers

Chronic pain management, Home-based therapy convenience, Physician or physiotherapist recommendation, Price and promotions, Product certification and safety assurance

Market Channels

Medical device distributors

Fit: Strong

Margin: Distributor margins are not disclosed in the evidence; wholesale discounts of 20-40% off list are typical in physiotherapy equipment supply.

Notes: Saudi Arabia has a well-developed medical equipment distribution sector, with 35 medical device distributor companies including Teriag, ProMedEx and Lana Medical Company. Appoint an established Riyadh- or Jeddah-based distributor with existing hospital and clinic relationships and SFDA-registered product lines.

Online retail (Amazon.sa, Noon)

Fit: Strong

Margin: Not disclosed in the evidence; online marketplaces typically compress margins through price competition.

Notes: Both platforms actively sell TENS units in Saudi Arabia with free shipping, free returns and cash on delivery, reaching consumers directly. List certified devices with Arabic and English product pages, competitive pricing and local fulfillment.

Market Channels

Physiotherapy and rehabilitation clinics

Fit: Moderate

Margin: Professional-grade devices retail between USD 100 and USD 500 or more, supporting higher per-unit margins.

Notes: Clinics are a natural professional buyer segment for TENS and EMS devices, and professional-grade devices command higher prices than home units. Target clinic chains and physiotherapy networks through distributor demonstrations and clinical training.

Hospitals and government health facilities

Fit: Moderate

Margin: Government tender pricing is highly competitive; a Saudi Ministry of Health tender anchor for electrodes was USD 0.35 per unit.

Notes: Government healthcare infrastructure investment is creating new hospitals and specialized facilities that can adopt TENS devices, but public tenders are price-competitive and subject to localization requirements. Partner with a local distributor experienced in government tenders and compliant with LCGPA economic participation requirements.

Competitive Landscape

Market leaders

Siemens Healthineers AG

Position: Named among the major companies operating in the Saudi electro-medical electrotherapeutic apparatus market.

Strength: Strong healthcare infrastructure presence and institutional credibility in Saudi Arabia.

Medtronic plc

Position: Listed among major companies in the Saudi electrotherapeutic apparatus market and among key global TENS machine players.

Strength: Global scale, broad medical device portfolio and established hospital relationships.

Omron Healthcare

Position: Named among leading players in the global electrotherapy device market and key TENS machine players.

Strength: Consumer health brand recognition and retail channel presence.

Competitive Landscape

Competing source markets

Europe

European brands such as Medi (Germany) and RZ-Medizintechnik (Germany) hold exclusive distributor arrangements in Saudi Arabia through local partners like Balikh.

China

China is Saudi Arabia's largest import partner at USD 39.73 billion (27.57%) in 2025, and an OEM bulk export price of USD 18.00 per 1,000 electrode pieces provides a low-cost manufacturing baseline.

United States

US brands benefit from established trade relationships and the second-largest import partner position at USD 11.76 billion in 2025.

Competitive Landscape

Where you can win Differentiate through SFDA-registered, SABER-certified portable or wearable TENS/EMS units with Arabic-language interfaces, competitive out-of-pocket pricing and reliable local after-sales support.

Barriers to entry

SFDA medical device registration

Severity: High

How to overcome: Engage an SFDA-registered authorized representative and align the quality management system with ISO 13485:2016 per SFDA MDS-G024 guidance.

SABER/Saleem conformity certification

Severity: High

How to overcome: Obtain a Certificate of Conformity through the SABER platform via a SASO-approved notified body before shipment.



Competitive Landscape

Limited insurance reimbursement

Severity: Medium

How to overcome: Price for the out-of-pocket consumer segment and pursue clinic and hospital channels where institutional budgets cover device purchases.

- Limited reimbursement coverage leaves a large out-of-pocket consumer segment underserved by premium-priced clinical

Gaps in the market

devices.



Competitive Landscape

- Wearable and wireless TENS devices are an emerging segment with fewer established competitors than conventional units.

- Arabic-language product support and localized marketing are not consistently offered by international brands.

Pricing

The figures below are source-report estimates or scenarios, not a quotation from the featured supplier. Confirm assumptions and actual costs before committing.

Retail price range

Entry-level home TENS units typically USD 20-50 per unit; professional-grade clinical devices USD 100-500 or more.

Wholesale expectation

Wholesale pricing often offers discounts of 20-40% depending on order volume, supplier agreements and geographic region.

Landed cost target

An OEM bulk export price from China of USD 18.00 per 1,000 electrode pieces provides a baseline for landed cost modeling.

Margin pressure

High



Pricing

Notes

Pricing evidence is drawn from global wholesale guidance and Middle East electrode anchors rather than Saudi retail scans; online marketplaces such as Amazon.sa and Noon compete heavily on price and promotions.

Price tiers

Entry-level home use

Range: USD 20-50 per unit

Note: Compact, affordable TENS units for home use, the most price-sensitive tier.

Professional/clinical

Range: USD 100-500 or more per unit

Note: Professional-grade devices used in clinical settings command higher prices.



Pricing

Electrodes and consumables

Range: USD 0.35 per unit (Saudi government tender) to USD 45.00 per box of 100 (UAE distributor list)

Note: Observed public anchors for electrodes in the Middle East; OEM bulk export price from China is USD 18.00 per 1,000 pieces.

Regulatory Requirements

Check the exact model

The following regulatory statements are retained from the source report, not independently verified. Confirm product classification, applicable standards, intended users and current requirements with qualified specialists.

The following preserves the source report's regulatory analysis, which has not been independently validated for this exact product. Requirements depend on classification, intended use and current rules. Confirm applicability with the destination authority or a qualified adviser.

SFDA medical device registration

Status: Mandatory

Authority: Saudi Food and Drug Authority (SFDA)

Detail: SFDA is the Saudi regulatory body for medical devices; CE marking may ease approval since SFDA is familiar with EU standards, but SFDA approval is a separate requirement.

Regulatory Requirements

ISO 13485:2016 quality management system alignment

Status: Mandatory

Authority: SFDA

Detail: SFDA MDS-G024 guidance harmonizes ISO 13485:2016 QMS requirements with SFDA-MDS regulations and applies to manufacturers, authorized representatives, importers and distributors.

SABER/Saleem Certificate of Conformity

Status: Mandatory

Authority: Saudi Standards, Metrology and Quality Organization (SASO)

Detail: Suppliers must register products through the SABER electronic portal and obtain a Certificate of Conformity from a SASO-approved notified body; the portal is accessible only to importers, approved certification bodies and Saudi customs officials.



Regulatory Requirements

RoHS approval for electrical/electronic devices

Status: Mandatory

Authority: SASO via the SABER platform

Detail: Suppliers of applicable electrical and electronic products must obtain RoHS approval through SABER in the form of a Certificate of Conformity issued by a SASO-approved notified body.

Import & Logistics

Check the exact model

The following regulatory statements are retained from the source report, not independently verified. Confirm product classification, applicable standards, intended users and current requirements with qualified specialists.

Estimated tariff

Saudi import duties generally range between 5% and 25%; electronics typically fall under HS code 8542 with a 5% import duty rate; the

effectively applied weighted average customs duty is 5.66%.



Import & Logistics

Suggested HS code

Saudi Arabia uses a 12-digit HS-based tariff system adopted across GCC states from January 2025; TENS/EMS devices should be classified under the appropriate 12-digit medical or electrical device code, with electronics often referenced under HS 8542.

Trade agreements

GCC member states apply a common external tariff, Saudi Arabia has signed trade agreements granting total exemption of customs duties to member countries

Typical lead time

Not specified in the evidence; the SABER conformity process can be complicated and lead to unnecessary charges if completed incorrectly, so certification should be completed before shipment.

Top source countries

China, United States, United Arab Emirates, India, Switzerland



Import & Logistics

Shipping notes

Saudi Arabia calculates duties and taxes using the CIF method, based on the value of imported goods plus shipping costs; customs brokers typically charge additional fees for filing clearance documents.



Buyer Expectations

Expectation

Importance

Regulatory certification and safety compliance SFDA registration and SABER Certificate of Conformity are required for lawful import and sale.

Must-have



Buyer Expectations

Affordable out-of-pocket pricing With only about 20% of regional insurance plans covering TENS, buyers are highly price-sensitive.

Must-have

Portability and ease of use Portable digital TENS devices lead the Middle East market due to convenience and multi-program settings.

Must-have



Buyer Expectations

Local after-sales support and consumables availability Reusable electrodes and lead wires are recurring purchases; buyers value reliable local supply and support.

Nice to have



Risks

1 Limited reimbursement coverage High Target out-of-pocket consumers with affordable pricing and pursue clinic and hospital channels where institutional budgets cover purchases.

2 Regulatory and conformity complexity High Complete SFDA registration and SABER certification before shipment and work with an experienced local importer or authorized representative.

3 Localization and Saudization requirements Medium Prepare economic participation plans with Saudi employment, local sourcing and training commitments for government and state-owned enterprise contracts.

4 Price competition from low-cost imports Medium Differentiate on certification, Arabic-language support, wearable innovation and reliable local distribution rather than competing solely on price.

Opportunities

1 Portable and wearable TENS devices for home use Portable digital TENS leads the Middle East market and wearable electrotherapy is an emerging global trend expanding home care adoption. How to capture: Launch a competitively priced, SFDA-registered portable or wearable unit through Amazon.sa, Noon and medical distributors.

2 Combination TENS & EMS devices Combination units are a distinct Middle East segment appealing to users wanting both pain relief and muscle stimulation. How to capture: Position a dual-function device for both consumer and physiotherapy clinic buyers.

3 Electrode and consumables supply Electrodes are recurring purchases with observed Middle East price anchors from USD 0.35 per unit to USD 45.00 per box of 100, and OEM bulk export pricing from China at USD 18.00 per 1,000 pieces. How to capture: Bundle electrodes with devices and offer competitive consumables pricing to distributors and online buyers.

4 Healthcare infrastructure build-out Government investment in new hospitals, medical centers and specialized facilities creates clinical adoption opportunities for TENS devices. How to capture: Partner with distributors experienced in government tenders and clinic supply.



Market Entry Strategy

Recommended approach

Enter through an established Saudi medical device distributor with SFDA-registered product lines, supported by online retail listings on Amazon.sa and Noon for the out-of-pocket consumer segment.

Estimated investment

Not specified in the evidence; costs include SFDA registration, SABER certification, distributor margins and inventory, with wholesale discounts of 20-40% off list typical in physiotherapy equipment supply.

Timeline

Not specified in the evidence; regulatory registration and conformity certification should be completed before shipment, and the SABER process can cause delays if completed incorrectly.

First steps



Market Entry Strategy

- Complete SFDA medical device registration and align the QMS with ISO 13485:2016 per SFDA MDS-G024 guidance.

- Obtain a SABER Certificate of Conformity through a SASO-approved notified body before shipment.

- Appoint a Riyadh- or Jeddah-based distributor with hospital, clinic and retail reach.

- List certified portable TENS/EMS units on Amazon.sa and Noon with Arabic and English product pages.



Trade Show Tips

- Prioritize events where Saudi medical device distributors and hospital procurement teams meet. - Saudi Arabia's distribution sector is the primary route to hospitals and clinics, and 35 medical device distributor companies operate in the market.

- Demonstrate portable and wearable devices with Arabic-language interfaces. - Portable digital TENS leads the Middle East market and localized support differentiates against international brands.

- Bring certification documentation and SFDA/SABER readiness evidence to meetings. - Regulatory compliance is a must-have buyer expectation and a common cause of shipment delays.



Action Brief

Do now Confirm SFDA registration pathway and appoint an authorized representative. Owner: Regulatory affairs

Do now Initiate SABER Certificate of Conformity application through a SASO-approved notified body. Owner: Compliance

This week Shortlist and contact Saudi medical device distributors such as Teriag, ProMedEx and Lana Medical Company. Owner: Business development

This month Prepare Amazon.sa and Noon listings with Arabic and English content and competitive pricing. Owner: E-commerce

Key Takeaways

1 Saudi Arabia is one of the three dominant Middle East TENS markets, within a regional TENS market estimated at USD 95 million and a Saudi electrotherapeutic apparatus market valued at USD 320 million in 2025 growing at 11.75% CAGR to USD 600 million by 2031.

2 Demand is anchored in a heavy chronic disease burden, with over 8 million people affected by diabetes and cardiovascular diseases and chronic diseases accounting for 73% of deaths.

3 Portable digital TENS devices lead the Middle East market, and wearable electrotherapy is an accelerating global trend.

4 Only about 20% of regional health insurance plans cover TENS devices, making out-of-pocket affordability a decisive purchase factor.

5 Entry requires SFDA registration, ISO 13485-aligned QMS, SABER Certificate of Conformity and typically a local distributor, with import duties commonly between 5% and 25% and electronics often at 5%.



COST STRUCTURE

See what the unit really carries.



Stack order: Ex-works / FOB unit price (China OEM, 500 units), Freight (sea LCL, China to Dammam/Jeddah), Insurance (0.5% of CIF) SAR, Import duty (CIF basis), VAT (15% on CIF+duty), SABER Certificate of Conformity (amortised over 500 units), SFDA medical device registration (amortised over 500 units), Customs clearance and inland delivery, Inbound QC, relabelling and Arabic manual, Warranty and returns provision (3%).

Calculated sums of the numeric source assumptions in SAR per unit, including VAT cash flow. The reconstructed base sum is SAR 140; the source states SAR 144. Resolve that difference and registration costs before quoting.

Landed Cost Model

The figures below are source-report estimates or scenarios, not a quotation from the featured supplier. Confirm assumptions and actual costs before committing.

Currency: SAR. Per unit: one portable dual-channel TENS+EMS combination unit with lead wires, 4 electrodes, rechargeable battery and carry case.

Ex-works / FOB unit price (China OEM, 500 units)

Best: SAR 60

Base: SAR 82 SAR

Worst: 110

Note: Derived from global entry-level TENS pricing of USD 20-50 retail and typical 20-40% wholesale discount; OEM FOB assumed at USD 16-29. Estimate, grade E.

Freight (sea LCL, China to Dammam/Jeddah)

Best: SAR 4

Base: SAR 7

Worst: SAR 12

Note: Assumes 500 units at ~0.6 kg each, LCL consolidation. No freight quote in evidence; conservative estimate, grade E.

Landed Cost Model

Insurance (0.5% of CIF)

Best: SAR 0.3

Base: SAR 0.5

Worst: SAR 0.7

Note: Standard marine cargo cover. Estimate, grade E.

Import duty (CIF basis)

Best: SAR 3 SAR

Base: 4.5

Worst: SAR 6

Note: Saudi duty range 5-25%; electronics cited at 5%. Applied 5% to CIF. Grade B/C - source is a freight forwarder guide, not the ZATCA tariff schedule.

Landed Cost Model

VAT (15% on CIF+duty)

Best: SAR 10

Base: SAR 14

Worst: SAR 19

Note: Saudi standard VAT rate; recoverable for VAT-registered importers, so treat as cash-flow not true cost. Grade A on rate, E on application.

SABER Certificate of Conformity (amortised over 500 units)

Best: SAR 4

Base: SAR 8

Worst: SAR 15

Note: Per-shipment CoC plus product registration amortised. No published fee found in evidence; estimate, grade E.

Landed Cost Model

SFDA medical device registration (amortised over 500 units)

Best: SAR 6

Base: SAR 12

Worst: SAR 25

Note: Registration and authorised-representative costs spread across first order. No fee schedule in evidence; estimate, grade E.

Customs clearance and inland delivery

Best: SAR 3

Base: SAR 6

Worst: SAR 10

Note: Broker fees plus last-mile to Riyadh/Jeddah warehouse. Estimate, grade E.

Landed Cost Model

Inbound QC, relabelling and Arabic manual

Best: SAR 3

Base: SAR 6

Worst: SAR 10

Note: Arabic labelling and IFU are typically required for the Saudi market.
Estimate, grade E.

Warranty and returns provision (3%)

Best: SAR 3

Base: SAR 4

Worst: SAR 6

Note: Electronics return rate assumption. Estimate, grade E.

True landed cost (base case)

Source estimate: SAR 144 per unit (excluding recoverable VAT: SAR 130)

Distributor sale price

Source estimate: SAR 210 per unit



Landed Cost Model

Retail price

Source estimate: SAR 320 per unit

Distributor margin

Source estimate: 31% on distributor sale price

Importer gross margin

Source estimate: 31% at SAR 210 transfer price against SAR 144 landed cost

Contribution per unit

Source estimate: SAR 66 per unit at base case

Assumptions behind these figures

- Order size 500 units; smaller orders raise per-unit freight and certification amortisation sharply.



Landed Cost Model

- Duty applied at 5% on CIF; the actual 12-digit HS line for TENS/EMS units was not confirmed in evidence and could be higher.

- VAT treated as recoverable; if the importer is not VAT-registered it becomes a real cost of SAR 14/unit.

- Certification and registration costs are estimates because no published SFDA or SABER fee schedule appeared in the evidence.

- Retail price anchored to observed global entry-level TENS pricing of USD 20-50 and Saudi online listings; no confirmed Saudi shelf price was found.

- Freight assumes sea LCL; air freight would roughly triple the freight line.

Break-Even Analysis

Before using this calculation

Inventory and working capital are cash requirements, not all fixed expenses. The source break-even estimate is provisional: separate investment, inventory and operating costs before making a commitment.

First order 500 units at base landed cost
SAR

72,000

The figures below are source-report estimates or scenarios, not a quotation from the featured supplier. Confirm assumptions and actual costs before committing.

SFDA registration, authorised
representative and ISO 13485
documentation SAR review

45,000



Break-Even Analysis

SABER product registration and first
Certificate of Conformity SAR

18,000

Arabic labelling, packaging adaptation and
sample testing SAR

15,000

Distributor onboarding, demo units and
initial marketing SAR Total setup cost SAR

180,000

30,000

Contribution per unit SAR 66:



Break-Even Analysis

Break-even volume 2,727 units:

Conservative monthly sales 120 units per month through one distributor plus direct clinic sales:

Estimated time to break even 23 months:

Assumptions



Break-Even Analysis

- Contribution per unit held at base case SAR 66; a 10% price erosion pushes break-even past 3,500 units.

- Setup costs exclude working capital tied up in inventory and exclude any listing or marketplace fees.

- Sales ramp assumes one active distributor; adding a second distributor could roughly halve time to break-even.

- No allowance for currency movement between SAR and USD/CNY, which is pegged but not risk-free on the cost side.

- Break-even is calculated on contribution, not net profit; overhead salaries are excluded.

Ideal Product Specification

Source this Source a CE-marked, ISO 13485-manufactured dual-channel TENS+EMS unit with Arabic IFU, rechargeable battery and 12+ programs at FOB under USD 22.

Modes

Requirement: Minimum 12 pre-set TENS and EMS programs

Why it matters: Portable digital multi-program units lead the Middle East segment.

Channels

Requirement: Dual channel, 4 electrode pads, independent intensity control

Why it matters: Matches the best-selling configuration observed on Saudi online retail.

Power

Requirement: Rechargeable lithium battery with USB-C charging

Why it matters: 9V battery units are being displaced by rechargeable home-care devices.

Ideal Product Specification

Certification

Requirement: CE mark plus ISO 13485:2016 manufacturer certificate

Why it matters: SFDA guidance aligns ISO 13485 with Saudi medical-device regulation and CE familiarity eases review.

Labeling

Requirement: Arabic and English instructions for use and packaging

Why it matters: Arabic labelling is standard expectation for Saudi retail and clinic procurement.

Safety

Requirement: RoHS compliance documentation for the SABER Certificate of Conformity

Why it matters: SASO electrical/electronic rules require RoHS approval via SABER.

Warranty

Requirement: Minimum 12 months, with spare electrode pads in the box

Why it matters: Electrodes are a consumable repeat-purchase driver and reduce early returns.

Ideal Product Specification

Packaging

Requirement: Hard carry case, retail-ready carton, barcode and country of origin

Why it matters: Required for both online listing and clinic resale.

Documentation

Requirement: Technical file, risk analysis and clinical rationale for TENS indications

Why it matters: SFDA registration requires a technical file; missing documents stall the whole launch.

Target FOB price

Estimate: USD 16-22 per unit at 500-1,000 units

Status: Source planning estimate, not a supplier quotation.

Target MOQ

Requirement: 500 units per SKU for the

Why it matters: first order



Ideal Product Specification

Deal breakers

- No Arabic labelling capability or willingness to private-label

- Manufacturer refuses to support SFDA registration documentation requests

- Manufacturer cannot supply ISO 13485 certificate or CE technical file

- Unit lacks RoHS documentation needed for SABER

Questions to Ask a Supplier

1

Can you provide a valid ISO 13485:2016 certificate and the full CE technical file for this exact model? Why: SFDA guidance aligns ISO 13485 with Saudi medical-device regulation; without it registration is not possible. Good answer: Current ISO 13485 certificate naming the exact manufacturing site, plus a complete CE technical file and declaration of conformity.

2

What is your FOB price at 500, 1,000 and 3,000 units, and what is the MOQ per model? Why: Per-unit economics and certification amortisation depend heavily on order size. Good answer: Tiered pricing with at least 15-20% reduction from 500 to 3,000 units and MOQ at or below 500.

Questions to Ask a Supplier

3

Have you exported this model to any GCC country, and can you share the registration or conformity documents used? Why: Prior GCC clearance signals the documentation package will survive Saudi review. Good answer: Named GCC or Middle East customers with verifiable registration or CoC references.

5

What is the warranty policy and how are defective units handled from Saudi Arabia? Why: Return logistics from Saudi Arabia are expensive and slow; warranty terms drive the provision line. Good answer: 12-month warranty with replacement-unit policy and a defined defect rate threshold for credit.

4 Can you supply Arabic and English IFU and retail packaging, and who bears the artwork cost? Why: Arabic labelling is expected in Saudi retail and clinic procurement. Good answer: In-house Arabic artwork capability with artwork cost included above a stated order quantity.

6

Can you provide RoHS test reports and any SASO-relevant test data? Why: SASO electrical/electronic rules require RoHS approval through SABER. Good answer: Third-party RoHS test reports less than two years old covering the exact model.

Questions to Ask a Supplier

What is your production lead time and how do you handle a repeat order mid-year? Why: Registration is per model; a supplier who cannot restock predictably breaks the clinic supply relationship. Good answer: Stated lead time under 45 days with a committed repeat-order slot.

9

What electrode pads do you supply and can we source replacements separately? Why: Electrodes are the repeat-purchase revenue stream and a key clinic retention lever. Good answer: Standard 2mm pin or snap connectors with a separate, competitively priced consumables price list.

8

Will you support SFDA registration by providing technical files, free sale certificates and change notifications? Why: Registration is the critical path and requires ongoing manufacturer cooperation, not just a one-off document dump. Good answer: Written commitment to supply and update registration documents for the life of the agreement.

Companies Worth Approaching

These are prospects or comparison companies named in the source report, not confirmed partners, authorised distributors or endorsements. Verify their current scope before contacting them.

Al-Ewan Medical Company <https://ameerahealth.com/country/saudi-arabia/>

Type: Medical equipment distributor

Why they fit: Established 1993, supplies medical services across Saudi Arabia and neighbouring countries.

Who to ask for: Procurement or business development manager

Priority: A



Companies Worth Approaching

FMS <https://ameerahealth.com/country/saudi-arabia/>

Type: Riyadh-based medical distributor

Why they fit: Leading Riyadh-based medical company established 1972 with hospital and clinic reach.

Who to ask for: Product manager, physiotherapy category

Priority: A

Balikh <https://ameerahealth.com/country/saudi-arabia/>

Type: Exclusive distributor for European medical brands

Why they fit: Holds exclusive Saudi distributorships for multiple European medical manufacturers, so understands brand onboarding.

Who to ask for: Managing director or category buyer

Priority: A



Companies Worth Approaching

Rose Aljazera <https://ameerahealth.com/country/saudi-arabia/>

Type: Medical, diagnostics and medical-cosmetics distributor

Why they fit: Local Saudi distributor established 2000 with regional Middle East reach.

Who to ask for: Procurement lead

Priority: B

ProMedEx https://tracxn.com/d/explore/medical-device-distributors-startups-in-saudi-arabia/__YCsf9q2rrO5SrRd4kfKheUH23Sdjv8HfdthmwGbRy0/companies

Type: Medical device distributor

Why they fit: Listed among the top medical device distributors in Saudi Arabia.

Who to ask for: Founder or commercial manager

Priority: B

Companies Worth Approaching

Lana Medical Company https://tracxn.com/d/explore/medical-device-distributors-startups-in-saudi-arabia/__YCsf9q2rrO5SrRd4kfKheUH23Sdjv8HfdthmwGbRy0/companies

Type: Medical device distributor

Why they fit: Listed among the top medical device distributors in Saudi Arabia.

Who to ask for: Procurement manager

Priority: B

Rustom Medical https://tracxn.com/d/explore/medical-device-distributors-startups-in-saudi-arabia/__YCsf9q2rrO5SrRd4kfKheUH23Sdjv8HfdthmwGbRy0/companies

Type: Medical device distributor

Why they fit: Listed among the top medical device distributors in Saudi Arabia.

Who to ask for: Category buyer

Priority: C



Companies Worth Approaching

OMC https://tracxn.com/d/explore/medical-device-distributors-startups-in-saudi-arabia/__YCsf9q2rrO5SrRd4kfKheUH23Sdjv8HfdthmwGbRy0/companies

Type: Medical device distributor

Why they fit: Listed among the top medical device distributors in Saudi Arabia.

Who to ask for: Commercial manager

Priority: C

Product-Market Fit by Segment

Physiotherapy and rehabilitation clinics

Their need: Affordable, reliable multi-program TENS+EMS units for in-clinic pain management and patient home-loan programmes

Fit: Strong

Price sensitivity: Medium

Sales difficulty: Medium

Home healthcare and elderly care providers

Their need: Portable, rechargeable, easy-to-use units for chronic pain self-management

Fit: Strong

Price sensitivity: Medium

Sales difficulty: Medium



Product-Market Fit by Segment

Online consumer buyers (Amazon.sa, Noon)

Their need: Low-cost drug-free pain relief with fast delivery and easy returns

Fit: Moderate

Price sensitivity: High

Sales difficulty: High

Sports and fitness recovery market

Their need: EMS muscle recovery and massage devices for athletes and gym users

Fit: Moderate

Price sensitivity: High

Sales difficulty: Medium



Product-Market Fit by Segment

Hospital pain-management departments

Their need: Clinical-grade electrotherapy with documented evidence and service support

Fit: Weak

Price sensitivity: Low

Sales difficulty: High



Who Should NOT Enter This Market

Sellers without an established Saudi importer of record

SABER portal access is restricted to importers, SASO-approved bodies and customs officials, so a foreign seller cannot self-clear.

Businesses expecting reimbursement-led demand

Only about 20% of health insurance plans in the Middle East cover TENS devices, so most buyers pay out of pocket.

High-volume, low-margin consumer electronics players

Medical-device registration and conformity costs per SKU make sub-SAR 100 retail pricing uneconomic.



Who Should NOT Enter This Market

Sellers unwilling to fund 3-6 months of registration before first revenue

SFDA registration and SABER certification sit on the critical path and cannot be compressed by paying more.

Validate Before You Invest

n The exact 12-digit HS code and applicable duty rate for TENS/EMS units
How: Ask a Saudi customs broker or the importer of record to classify the product on the SABER platform and confirm the duty line Why: Duty drives landed cost and a wrong classification causes delays, penalties and rework

n Real Saudi retail and clinic selling prices for comparable TENS+EMS units
How: Mystery-shop Amazon.sa, Noon and three Riyadh physiotherapy clinics for actual transaction prices Why: The margin model depends on a retail price that was inferred, not observed

n Actual SFDA registration pathway, fees and timeline for a Class A/B TENS device
How: Engage an SFDA-registered authorised representative for a written scope, fee and timeline quote Why: Registration is the critical path; a wrong assumption here invalidates the whole entry budget

n Whether any Saudi distributor will commit to a minimum purchase and marketing support
How: Request written letters of intent from two or three of the named distributors before placing the first order Why: Without a committed channel partner the break-even timeline roughly doubles



Validate Before You Invest

Actual freight, clearance and last-mile cost from China to a Riyadh warehouse

How: Obtain three forwarder quotes for a 500-unit LCL shipment to Dammam or Jeddah Why: Freight and clearance were estimated and could move the landed cost by 10-15%



What We Know and What We Do Not

Known

- Saudi Arabia uses a 12-digit HS system with CIF-based duty and VAT assessment

- Insurance reimbursement for TENS in the Middle East is limited

- Saudi Arabia requires SABER conformity and SFDA registration for medical devices

- There is an established pool of Saudi medical-device distributors actively adding lines

Likely



What We Know and What We Do Not

- TENS/EMS units will attract a low single-digit duty rate as electronics, but this is not confirmed for the specific HS line

- Arabic labelling and IFU will be required for retail and clinic sales

- A Saudi distributor will demand exclusivity in exchange for registration support

Unknown

- Actual Saudi unit volumes and value for TENS/EMS specifically

- Actual SFDA registration fees and review timelines for this device class



What We Know and What We Do Not

- Actual SABER Certificate of Conformity cost per shipment

- Real transaction prices paid by Saudi clinics and consumers

- Whether any Saudi public tender actively procures TENS devices

Needs verification

- 12-digit HS classification and duty rate

- SFDA device classification and registration pathway



What We Know and What We Do Not

- Freight and clearance quotes from three forwarders

- Written distributor interest and minimum order commitments

- Competitor shelf prices on Amazon.sa and Noon

Evidence Quality

A government or regulator · B industry body · C research firm · D trade observation · E estimate or inference

Overall evidence grade: C Market sizing and growth come from commercial research firms with inconsistent figures and no Saudi-specific TENS volume data. Regulatory and trade-process evidence is stronger and comes from government and official trade sources. Pricing and cost lines are largely inferred.

Saudi Arabia applies a 12-digit HS tariff system and requires SABER conformity for regulated products

Grade: A

Basis: US International Trade Administration country commercial guide

SASO requires RoHS approval via SABER for applicable electrical and electronic products

Grade: A

Basis: UL Solutions regulatory update on SASO rules

Evidence Quality

SFDA guidance aligns ISO 13485:2016 with Saudi medical-device regulation for manufacturers, importers and distributors

Grade: A

Basis: SFDA MDS-G024 guidance as reported by a regulatory consultancy

Saudi Arabia's effectively applied weighted average customs duty is 5.66%

Grade: A

Basis: World Bank WITS country trade statistics



Evidence Quality

Middle East TENS market is valued at USD 95 million with Saudi Arabia, UAE and Egypt as key markets

Grade: C

Basis: Ken Research Middle East TENS market report

Only about 20% of health insurance plans in the Middle East cover TENS devices

Grade: C

Basis: Ken Research Middle East TENS market report



Evidence Quality

Global entry-level TENS units retail at USD 20-50 and wholesale discounts run 20-40%

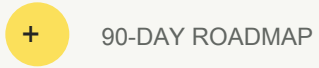
Grade: D

Basis: Distributor/wholesaler commentary on physiotherapy equipment pricing

Saudi Arabia's electrotherapeutic apparatus market is worth USD 320 million in 2025 growing at 11.75% CAGR

Grade: C

Basis: Ken Research Saudi Arabia electrotherapeutic market report

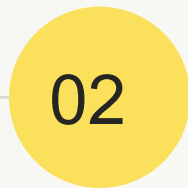


Validate. Build. Measure.



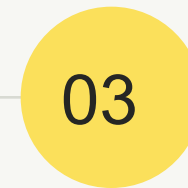
Days 0-30

Confirm exact device classification, qualified Saudi representation and distributor interest.



Days 31-60

Obtain model-specific documents, written regulatory timelines and revised unit economics.



Days 61-90

Review signed purchase interest and contribution gates; do not sell before required authorisation.

A conditional action plan, not a guaranteed 90-day launch. The source gives 4-7 months from purchase order to first sale; authorisation and qualified local representation remain the critical path.



30 / 60 / 90 Day Plan

0-30 days Regulatory and cost reconnaissance

- Ask a Saudi customs broker to confirm the 12-digit HS code and duty rate for the product

- Mystery-shop Amazon.sa, Noon and three Riyadh physiotherapy clinics to record actual selling prices

- Engage an SFDA-registered authorised representative and obtain a written registration scope, fee and timeline for a dual-channel TENS+EMS unit

- Obtain three forwarder quotes for a 500-unit LCL shipment from China to Dammam or Jeddah

- Shortlist five Saudi medical-device distributors from the named list and request introductory calls 31-60 days Supplier and partner qualification



30 / 60 / 90 Day Plan

- Request ISO 13485 certificates, CE technical files and RoHS reports from three Chinese OEMs

- Hold discovery calls with the shortlisted Saudi distributors and test appetite for a minimum purchase commitment

- Decide whether the revised contribution per unit still supports a 24-month break-even 61-90 days Pilot order and registration filing

- Negotiate FOB pricing at 500 and 1,000 units and confirm Arabic labelling capability

- Build a revised landed-cost model using real freight, duty and certification quotes

- Place a 500-unit pilot order with the selected OEM against a 30% deposit



30 / 60 / 90 Day Plan

- File SFDA registration and SABER product registration through the chosen importer of record

- Sign a non-exclusive pilot agreement with one Saudi distributor covering 6 months and a minimum order

- Prepare Arabic IFU, retail packaging and clinic demo units

- Set up a simple sell-through tracker to measure monthly units and reorder rate

Go / No-Go trigger Commit to a full launch only if, within 90 days, SFDA registration is filed with a written timeline under 6 months, at least one Saudi distributor signs a minimum purchase commitment, and the revised landed cost keeps contribution per unit above SAR 55.



Alternative Markets to Consider

United Arab Emirates

ctohnissider: Larger per-capita medical device spend, faster import clearance and Easier a strong re-export hub function for the wider Gulf.

Kuwait Qatar

ctohnissider: High healthcare spend per capita and smaller, Similar less crowded distributor landscape than Saudi Arabia.

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Sources

This report is compiled from publicly available third-party sources market valuations in particular differ widely across research firms. Saudi Food and Drug Authority, SASO and a qualified customs broker investment advice.

and market research publications. Figures are estimates and may vary between sources; global TENS Regulatory requirements, tariff rates and certification procedures should be verified with the before commercial decisions are made. This document does not constitute legal, regulatory or



WORK WITH US

From a report to a real next step.

1

Understand

My Fair organizes supplier intelligence, products and public-source evidence. AI supports analysis and language understanding; it does not certify a supplier.

2

Coordinate

Ask about supplier follow-up, factory visits, quotations, OEM/ODM, packaging and document coordination. Scope, qualified partners, fees and timelines are agreed individually.

3

Build your own

Need this workflow for your business? StructuredLayer can discuss a custom AI-assisted system built around your team and requirements.

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