Gulf Market Entry: *a strategic insider's guide* for medical device companies

The complete regulatory, commercial and cultural playbook: from first registration to signed distribution agreement.

Saudi Arabia | UAE | Qatar | Kuwait | Bahrain | Oman

Maiol Tomás · Co-founder @ 6 degrees · Fractional Export Director · Europe · GCC/UAE

Version: October 2026

What this guide *covers*

01 Six Gulf markets, six regulators

02 The commercial agency law trap

03 Public tenders vs. private sector

04 Reimbursement and health insurance

05 Local content and partnerships

06 Distributor archetypes

07 Cultural dynamics and negotiation

08 Entry windows: industry conferences

09 Pre-travel checklist

10 The six mistakes that cost the most

11 Glossary of acronyms

The Gulf, in *six numbers*

6

national regulators, and no single GCC-wide device registration

$12–13B

estimated GCC medical device market, 2026 (Source: P&S Intelligence)

~80%

of GCC device spend concentrated in Saudi Arabia and the UAE combined

40%

minimum local content to qualify for Saudi's "Made in Saudi" tender advantage

35 days

average SFDA MDMA technical review once a complete file is submitted

3 ARs

control more than 54% of all registered devices in Bahrain alone

Six markets, *one European habit*

European medical device companies tend to arrive in the Gulf with a European mental model: get the CE mark, find a distributor, sign an exclusive, and let the relationship do the rest. That model works in Germany. It does not work between Riyadh and Muscat.

The six Gulf states regulate, buy and negotiate differently, and those differences are written into law and procurement architecture. This guide goes deep into each of them: what changes, why it changes the outcome, and what to do about it before you sign anything.

It is written for CEOs and Export Directors of companies that already have a validated product and have decided to build a presence across Saudi Arabia, the UAE, Qatar, Kuwait, Bahrain and Oman. The open question is how.

THE ASSUMPTION THAT COSTS THE MOST

Treating Gulf entry as a faster, hotter version of a European launch. It runs on its own regulatory, procurement and social logic, and all three have to be right before a single unit sells.

The Gulf *at a glance*

Same customs union, six different regulators, six different tolerances for a CE mark as a shortcut.

Saudi Arabia

SFDA

Largest GCC healthcare market, roughly 52% of regional device spend. Abridged CE/FDA route closed in 2022.

UAE

EMIRATES DRUG ESTABLISHMENT

~28% of regional device spend. Oversight moved from MOHAP to EDE across 2025.

Qatar

MINISTRY OF PUBLIC HEALTH

CE/FDA accepted as classification basis. Currently only implantable devices require registration.

Kuwait

MINISTRY OF HEALTH

Structured framework under Decree 387/2025, with an abridged reference-market pathway.

Bahrain

NHRA

Mandatory registration from Feb 2026. Three Authorized Representatives control over 54% of listings.

Oman

MINISTRY OF HEALTH

New electronic registration portal since Aug 2025; phased mandatory deadlines through July 2026.

Regulatory pathways, *side by side*

MARKET	REGULATORY BODY	CE / FDA RELIANCE	TYPICAL TIMELINE
Saudi Arabia	SFDA: MDMA (Medical Device Marketing Authorization)	Independent technical review; CE/FDA support the file, do not replace it	~35 working days (Class I listing: 4 days)
UAE	Emirates Drug Establishment (from MOHAP, 2025)	High reliance on CE/FDA under the reliance-based model	~45 working days
Qatar	Ministry of Public Health (MoPH)	CE/FDA accepted as classification basis	Varies; implantables currently in scope
Kuwait	Ministry of Health (Decree 387/2025)	Abridged pathway accepts reference-market approvals	Multiple review tracks, 2–4 months typical
Bahrain	National Health Regulatory Authority (NHRA)	Accepts reference-market approvals; fast-track available	Predictable: electronic Ajheza system
Oman	Ministry of Health (e-portal since 2025)	Reference-market reliance; phased mandatory registration	Phased deadlines through July 2026

Every market requires its own local Authorized Representative. None of these approvals transfer automatically to another GCC country, despite the shared customs union.

Inside the SFDA's *MDMA process*

Saudi Arabia classifies devices into four risk classes (A, B, C and D), closely mirroring the EU MDR's Class I, IIa, IIb and III. Class A/B products can qualify for the Medical Device National Registry (MDNR) listing route: a lighter process, reviewed in roughly four working days.

Higher-risk devices go through the Medical Device Marketing Authorization (MDMA) pathway: a full Technical File Assessment submitted via the SFDA's GHAD portal. Since January 2022, this is the only route available. The old GHTF pathway that accepted CE or FDA approval as sufficient on its own was discontinued. CE and FDA approval still strengthen a file, but SFDA runs its own review.

Up to 50 devices can be bundled into a single MDMA application if they share class, manufacturer and intended use, a meaningful efficiency for companies with broad product lines. Certificates are typically valid for three years.

35 days

average MDMA technical review once the file is complete

50 devices

maximum per bundled application

3 years

typical MDMA certificate validity

A regulator *in transition*

The UAE's device registration authority changed mid-cycle. Federal Decree-Law No. 38 of 2024, in force since January 2025, created the Emirates Drug Establishment (EDE) and transferred device and pharmaceutical registration away from the Ministry of Health and Prevention (MOHAP). The handover of all 44 core regulatory services completed by the end of 2025, so a registration filed under the old MOHAP regime should not be assumed to carry over untouched.

The UAE also enforces Tatmeen, a mandatory track-and-trace platform with GS1 serialization on secondary packaging. Regulatory approval alone does not permit a product to move through the supply chain.

Emirate-level nuance matters too. Dubai Healthcare City (DHCC) permits 100% foreign ownership and runs its own layer of oversight alongside federal EDE registration, while Abu Dhabi's DOH and Dubai's DHA each add emirate-specific requirements on top of the federal baseline.

Jan 2025
MOHAP to EDE transition began

45 days
typical regulatory review timeline

5 years
device registration validity once approved

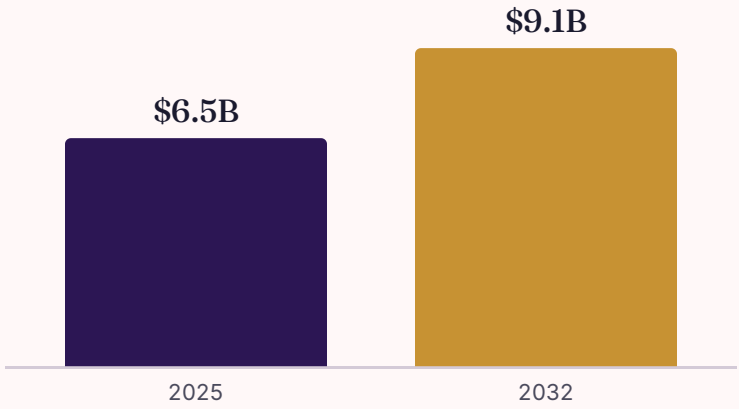
Where the spend *actually sits*

GCC device market share, 2026 est.



Saudi Arabia + UAE ≈ 80% of GCC medical device spend. Source: BioNixus, 2026 estimate. Figures vary by research firm.

Saudi Arabia device market growth



~5.0% CAGR, 2026–2032. Source: P&S Intelligence.

UAE: registered agency *vs. ordinary contract*

In the UAE, an agreement appointing a distributor, agent, licensee or franchisee within a defined territory can qualify as a registered commercial agency under Federal Law No. 3 of 2022. The distinction below is the single most consequential legal decision in a Gulf market entry, and it is usually made by accident.

FACTOR	REGISTERED COMMERCIAL AGENCY	ORDINARY DISTRIBUTION CONTRACT
Exclusivity	Exclusive by law within its registered territory (Art. 7)	Only if the contract says so; no statutory exclusivity
Termination	Hard to terminate without cause; statutory notice rules apply	Governed by the contract and general Commercial Transactions Law
Compensation	Agent may be entitled to compensation, sometimes even for sales the principal makes directly	No special statutory compensation regime
Registration	Ministry of Economy Commercial Agencies Register	Not registered as a commercial agency
Free zones	Federal law generally does not apply inside DIFC, ADGM, JAFZA, DMCC, etc.	Same: free zone activity follows its own framework

Saudi Arabia and *the wider Gulf*

Saudi Arabia's agency law goes further at the outset. A registered commercial agent must be a Saudi national or a wholly Saudi-owned entity, and the agreement must be concluded directly with the manufacturer, with no intermediary in the principal's home country. To carry legal weight, it must be registered with the Ministry of Commerce's Commercial Agencies Register, and the contract must explicitly address spare parts, maintenance and warranty obligations, including one year after the agreement ends.

An unregistered arrangement, however it is worded, does not receive the same statutory protection. That sounds like flexibility, until the company realizes its "exclusive distributor" has no standing to enforce anything either.

Qatar, Kuwait, Bahrain and Oman each maintain their own commercial agency or commercial registration regimes, generally requiring a locally licensed agent or a minimum level of local ownership to act as registered representative. The specifics (exclusivity defaults, termination notice, compensation rules) vary by country and change periodically. Treat each as its own legal review, separate from the UAE or Saudi model.

> *The distributor who insists on registering the agency immediately is not being helpful. They are locking in rights that will outlast your patience with them.*

Red flags *before you sign*

1

Registers before selling

The candidate pushes to register the agency before any sales history or pilot period exists.

2

Vague territory

The agreement is silent on whether the territory is one emirate, the whole UAE, or a country-wide Saudi appointment.

3

No real exit clause

Termination language says little beyond “mutual agreement”, with no defined cause, notice period or compensation formula.

4

Exclusivity before registration

The distributor wants exclusivity locked in before your device registration is even filed.

Inside NUPCO: *Saudi Arabia's buyer of buyers*

The National Unified Procurement Company (NUPCO) was established by Royal Decree in 2009 and is wholly owned by Saudi Arabia's Public Investment Fund. It is the largest centralized medical procurement, warehousing and distribution entity in the Kingdom, aggregating demand across the entire Ministry of Health hospital network into framework tenders, rather than each hospital buying independently.

Government purchasing represents more than half of total healthcare spend in Saudi Arabia, and "Made in Saudi" products increasingly carry a scoring advantage in NUPCO framework agreements. In some reported cases, a qualifying local product excludes a foreign-only bid from proceeding at all.

Bidding requires a bid bond (typically 1–2% of contract value, issued by a Saudi-licensed bank) and a performance bond (5–10%) upon award. Foreign vendors can usually issue these through international banks with Saudi correspondent relationships.

2009

NUPCO established by Royal Decree

>50%

of Saudi healthcare spend runs through government procurement

1–10%

bid and performance bond range on NUPCO tenders

Procurement channels *across the Gulf*

MARKET	PUBLIC PROCUREMENT CHANNEL	NOTE
Saudi Arabia	NUPCO (centralized) + Etimad tender portal	Framework agreements, local-content scoring
UAE	Emirate-level: DOH (Abu Dhabi), DHA (Dubai)	Federal EDE registration is a prerequisite either way
Qatar	Hamad Medical Corporation + MoPH tenders	HMC dominates public hospital demand
Kuwait	Ministry of Health central tenders	Centralized MOH purchasing for public facilities
Bahrain	MOH / NHRA-linked tenders	Smaller volumes, concentrated AR landscape
Oman	Ministry of Health central tenders	Centralized MOH purchasing, phased digitization

Public tenders

Centralized buyer, framework agreements, bid and performance bonds, local-content scoring, and sales cycles measured in procurement rounds rather than quarters.

Private sector

Direct hospital and clinic relationships, faster decisions, and clinical evidence that carries more weight than local manufacturing, with a shorter, more relationship-dependent cycle.

Who actually pays: *Saudi Arabia & UAE*

Saudi Arabia is moving toward a structured, insurance-based system under its Council of Health Insurance (CHI) and the NPHIES claims platform, while government procurement through NUPCO still covers the bulk of public hospital volume. Expect both channels to matter for years to come, with no clean handover from one to the other.

More than 60 insurers operate in the UAE alone, so a device's reimbursement pathway can vary by emirate even within one country.

> *A device with no reimbursement pathway can still sell in the Gulf. It becomes a private-pay or self-insured-employer sale, which changes who your first ten customers actually are.*

EMIRATE	SCHEME	COVERS
Abu Dhabi	Thiqa (via Daman)	Comprehensive coverage for nationals
Abu Dhabi	Employer-mandated private insurance	Covers expatriates
Dubai	Dubai Health Insurance Law (DHA)	Employer-provided insurance mandate
Northern Emirates	Basic Health Insurance Scheme (from Jan 2025)	Extended to private-sector employees & domestic workers

Qatar, Kuwait, *Bahrain and Oman*

The four smaller Gulf states still lean more heavily on direct government health budgets than on private insurance claims. Several have introduced or expanded mandatory expatriate health insurance schemes over the past few years, but the structure is less standardized, and changes faster, than in Saudi Arabia or the UAE. This shifts the commercial conversation back toward the procurement relationship rather than a payer negotiation, and it means the reimbursement question has to be asked fresh in each country rather than assumed from a neighbor's model.

A European company used to negotiating with a national health service or a handful of insurers should expect to have this conversation multiple times, with different counterparts, inside a single regional entry.

> PRACTICAL TAKEAWAY
>
> *For Qatar, Kuwait, Bahrain and Oman, verify the current reimbursement and insurance framework directly with the local Ministry of Health or Authorized Representative before pricing. These frameworks are actively evolving and should not be assumed from public sources alone.*

Saudi Arabia: *from Vision 2030 to the tender scoresheet*

A product needs to demonstrate a minimum local content threshold, currently around 40%, to qualify for the “Made in Saudi” designation. That status brings preferential scoring in NUPCO framework agreements, mandatory-list inclusion under the Local Content and Government Procurement Authority (LCGPA), and access to industrial incentives through the National Industrial Development and Logistics Program (NIDLP): subsidized industrial land, preferential energy pricing, and financing via the Saudi Industrial Development Fund (SIDF).

Crucially, the SFDA’s own guidance (MDS-G11 v2.0) explicitly recognizes partial local manufacturing (final assembly, packaging or labeling inside the Kingdom) as a valid path. That is considerably less capital-intensive than building a full factory, and it is the realistic entry point for most European companies rather than a full production line on day one.

~40%

local content threshold for “Made in Saudi” status

2018

NUPCO strategy pledging priority to local content in the medical supply chain

Source: Oxford Business Group, The Report: Saudi Arabia 2022

89%

of NUPCO supply chain contracts went to local partners in 2021

Source: Oxford Business Group, The Report: Saudi Arabia 2022

UAE: the *In-Country Value (ICV)* program

The UAE runs its own localization framework through the Ministry of Industry and Advanced Technology's National In-Country Value (ICV) Program, launched under "Projects of the 50." It measures how much economic value a company generates inside the UAE (local procurement, manufacturing, investment, and Emirati employment), and a stronger ICV score directly improves standing in government and government-linked tenders. Medical devices are named as one of twelve priority sectors under the related Make it in the Emirates (MIITE) industrial procurement program.

The effect is visible at scale: PureHealth, the largest healthcare group in the Middle East, has surpassed AED 6.33 billion (about $1.72 billion) in cumulative local procurement spend since joining the ICV program in 2022, with a target of AED 13 billion by 2032. Its ICV performance is now a factor considered across its network, including its insurance and lab entities.

> *For a European supplier, the useful question is "what is our ICV-certifiable local spend?" Local distribution, warehousing, assembly or service operations all count, and a certified score can matter as much as the product itself in a PureHealth-scale tender.*

Three ways to play *the local-content question*

APPROACH	CAPITAL	TIME TO MARKET	TENDER ELIGIBILITY	BEST FOR
Import-only	Low	Fast	Private sector & smaller government purchases	Testing market fit before committing capital
Partial local assembly / packaging	Medium	Medium	Improves scoring; can meet “Made in Saudi” threshold	Mid-volume products targeting government channels
Full local manufacturing	High	Slow (years)	Maximum tender eligibility + NIDLP / SIDF incentives	Large-volume, long-term regional commitment

> *Decide which game you are playing, and tell your distributor clearly, before the relationship starts. Mismatched expectations here surface six months in, not on day one.*

Four kinds of *“distributor”*

Not every company that calls itself a distributor plays the same role. Before comparing candidates, know which of these four you are actually talking to.

1

The diversified trading house

Large local conglomerate with a healthcare division alongside unrelated business lines. Strong government relationships and capital, limited clinical depth: your product competes internally for attention.

2

The specialized medical distributor

Healthcare-only, smaller, with deep clinical relationships and a sales team that understands the product. Less leverage in public tenders, more credibility with clinicians and private hospitals.

3

The registration-only agent

Holds the regulatory license and local relationship needed to register the device, but little real commercial infrastructure behind it. Common in smaller Gulf states; useful for compliance, rarely sufficient for growth.

4

The government-adjacent partner

Close ties to a specific ministry, hospital group or procurement body. Opens a single channel fast, but the relationship can become a ceiling once you need to sell beyond it.

Scoring *the four archetypes*

ARCHETYPE	CLINICAL DEPTH	GOVERNMENT ACCESS	CAPITAL & WAREHOUSING	GEOGRAPHIC REACH
Diversified trading house	Low–Medium	High	High	Broad, multi-city
Specialized medical distributor	High	Medium	Medium	Clinical hubs
Registration-only agent	Low	Low–Medium	Low	Single country, narrow
Government-adjacent partner	Medium	High (single channel)	Medium	Deep but narrow

This is a practitioner's evaluation framework, not a market ranking. Use it to structure your own due diligence conversations, weighted by which channel (public tender vs. private/clinical) matters most for your product.

Timing: *Ramadan and the business calendar*

Ramadan shifts roughly ten days earlier each Gregorian year and compresses working hours across the region for its full duration: public-sector hours typically shorten, and business pace slows noticeably in the final ten days before Eid al-Fitr. Scheduling a first meeting, a tender deadline, or a distributor renewal inside that window, without accounting for it, reads as not having done the homework.

Exact dates depend on moon sighting and can shift by a day or two from the astronomical projection.

	EXPECTED START	EXPECTED END
Ramadan 2026	~Feb 17–18, 2026	~Mar 18–19, 2026
Ramadan 2027	~Feb 8–9, 2027	~Mar 9–10, 2027

Dates are astronomical projections (Umm al-Qura calendar), subject to official moon-sighting confirmation in each country.

> *Build a buffer of at least three to four weeks around Ramadan and Eid into any Gulf timeline. Tender deadlines, distributor negotiations and registration follow-ups all slow down, and pushing for urgency during this window damages the relationship more than it saves time.*

Decision-making *and presence*

None of this is etiquette advice. Each factor has a direct, measurable effect on how long a Gulf deal takes to close, and whether it closes at all.

Hierarchy

Authority is frequently more personal and less delegated than in a European organization. The person you negotiate with is often not the person who decides. Identifying who actually holds that authority, early, determines how long the process takes.

Pace

Decisions often move in bursts rather than steadily: fast once trust is established, slow while it is being built. Pushing a European quarterly cadence onto a relationship still in the trust-building phase usually backfires.

Presence

Relationships are built in person, repeatedly, before they are built on paper. A distributor who has met you twice in the region treats the partnership differently than one who has only exchanged emails, regardless of what the contract says.

Do’s and don’ts *at the table*

Do

- Visit in person before signing anything meaningful.
- Identify the true decision-maker, separate from whoever replies to the first email.
- Build buffer time around Ramadan, Eid and the summer months into every timeline.
- Confirm which language version of the contract is authoritative if the two ever conflict.

Don’t

- Assume fast email replies signal seriousness, or slow ones signal disinterest.
- Schedule a critical negotiation in the week before Eid.
- Treat a large trading house’s enthusiasm as proof of commercial traction.
- Sign exclusivity before your device registration is even filed.

The Gulf healthcare *conference calendar*

EVENT	DATES	VENUE	WHY IT MATTERS
WHX Dubai (formerly Arab Health)	25–28 Jan 2027	Dubai Exhibition Centre	The region’s largest healthcare gathering: broadest cross-section of distributors and buyers
WHX Labs Dubai (formerly Medlab Middle East)	26–29 Jan 2027	Dubai World Trade Centre	Laboratory and diagnostics focus, runs alongside WHX Dubai
Global Health Exhibition	Annual	Riyadh	Saudi-specific counterpart to Dubai; 2025 edition reported $35.5B in signed deals (Source: Global Health Exhibition 2025 Show Report)

Exact recurring dates for smaller national events (Qatar, Kuwait, Bahrain, Oman healthcare exhibitions) should be checked annually. The WHX and Global Health calendars above are the two fixed anchors worth planning a full year around.

Turning a conference *into a pipeline*

The Gulf's healthcare calendar gives European companies a small number of concentrated windows to meet distributors, regulators and buyers in one place, instead of touring six countries separately. Treating these events as a place to hand out brochures wastes the opportunity. They are the one moment in the year when a company can meet three or four candidate distributors from different countries within the same three days, compare them directly against the archetypes in Section 6, and start the qualification conversation before committing to any single market.

> *A conference stand generates leads. A conference itinerary planned around your shortlist of candidate distributors, with meetings booked before you land rather than scheduled from the booth, generates a pipeline.*

Phase 1 · *Strategic prep* (12–6 months out)

1 Verify the pathway, not the assumption

Confirm your device's classification and how each target country treats your CE or FDA approval today. Saudi Arabia's abridged route closed in 2022 and the UAE changed regulator in 2025.

2 Choose the legal structure before the relationship

Decide whether each market relationship should be a registered statutory agency or an ordinary distribution contract, and draft the agreement accordingly.

3 Take a position on local content

Import-only, partial assembly, or full localization: know which one you are offering before a distributor or a tender asks.

4 Find the real decision-maker

Identify who actually holds authority on the distributor's side, separate from who replies to the first email.

Phase 2 · *Operational prep* (final weeks)

1 Map the calendar before the flights

Check Ramadan dates, the relevant industry conference, and the tender cycle of your priority market before committing travel dates.

2 Write your reimbursement position

One page per priority market: public procurement, private insurance, or self-pay, and what that means for your first ten customers.

3 Shortlist by archetype, not by speed of reply

Score distributor candidates against the archetypes in Section 6 before the first call, not after.

4 Start the Arabic documentation early

Labeling and technical file translation take longer than expected. Begin before you have finalized which market comes first.

The six mistakes *that cost the most*

01

Treating the CE mark as a Gulf-wide passport

It stopped being one in Saudi Arabia in 2022, and the UAE just changed regulator.

02

Registering a commercial agency before understanding what it locks in

A five-page distribution agreement can become the hardest contract in the portfolio to unwind.

03

Building a private-sector playbook for a public-tender market

NUPCO buys for the whole system, far beyond the reach of a single hospital purchasing office.

04

Ignoring reimbursement until after the distributor is signed

Who pays changes who your first ten customers actually are.

05

Deciding on local content after the tender, not before

By then it's too late to qualify for the scoring advantage, or the incentives.

06

Picking a distributor by enthusiasm, not archetype fit

The most excited candidate is not always the one who can actually open the channel you need.

Glossary *of acronyms*

SFDA	Saudi Food and Drug Authority
EDE	Emirates Drug Establishment
DHA / DOH	Dubai Health Authority / Abu Dhabi Dept. of Health
MoPH	Ministry of Public Health (Qatar)
CHI / NPHIES	Council of Health Insurance / National Platform for Health Information Exchange Services
NIDLP	National Industrial Development and Logistics Program (Saudi Arabia)
AR / LAR	Authorized Representative / Local Authorized Representative
MDMA	Medical Device Marketing Authorization (Saudi Arabia)
MOHAP	Ministry of Health and Prevention (UAE, pre-2025 device authority)
NHRA	National Health Regulatory Authority (Bahrain)
NUPCO	National Unified Procurement Company (Saudi Arabia)
ICV	In-Country Value program (UAE)
LCGPA	Local Content and Government Procurement Authority (Saudi Arabia)
GCC	Gulf Cooperation Council

The Gulf does not punish ambition. *It punishes assumptions.*

Eleven sections, six countries, and one recurring pattern: the questions this guide answers are the same questions any market entry requires. Which regulator reviews your file, whether your distributor agreement is a contract or a statutory relationship, who is really paying for the device, and who in the room actually decides. The Gulf simply answers them differently than Brussels or Berlin does, and the cost of guessing wrong is a signed agreement that takes years to unwind.

Which of these eleven sections *still needs an answer for your product?*

A thirty-minute diagnostic call is enough to tell you which questions in this guide still need answers for your specific product and market: the regulatory pathway, the distributor structure, the local-content position, or the reimbursement route.

Book your 30-min diagnostic

calendly.com/mtomas-6degrees/30min

FRACTIONAL EXPORT DIRECTOR · 6 DEGREES · EUROPE & GCC

Maiol *Tomás*

Co-founder of 6 degrees. Builds and runs the distributor pipeline for European Medical Device and HealthTech companies entering Europe and the GCC, from qualification to signed agreement.

calendly.com/mtomas-6degrees/30min