

Japan, Without the Detours

The five decisions that set your timeline

A practical guide for medical device, diagnostics and healthcare AI companies considering Japan.

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CarbGeM Inc. · Tokyo and Kobe, Japan · carbgem.com/en

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Executive summary

Japan is one of the largest healthcare markets in the world, and since 2020 its regulators have rewritten the rules for software-based medical devices in the direction overseas developers want: a single consultation window, published review points by product type, and a two-step approval path. The market is open. What is still missing, for most overseas companies, is the map.

Entering Japan is not one decision. It is five, and the order in which you make them decides how long the whole thing takes:

	Decision 1 Your regulatory route	What class is the product in Japan, and is it approval (<i>shonin</i>), certification (<i>ninsho</i>) or notification (<i>todokede</i>)?
	Decision 2 Your evidence	Will your existing data carry, or do you need Japanese data — and if so, how much and of what kind?
	Decision 3 Your clinical partner	Which Japanese hospital or academic group will stake its name on your product, and what do they need to see first?
	Decision 4 Your presence in Japan	A subsidiary, a Japanese marketing authorization holder, or approval in your own name with a designated holder?
	Decision 5 Your commercial route	Reimbursed or not, and through whom?

✓ Decisions 1–3 are made together, first

→ Decisions 4–5 are locked afterwards

Figure 2 — The five decisions, and the order that saves time.

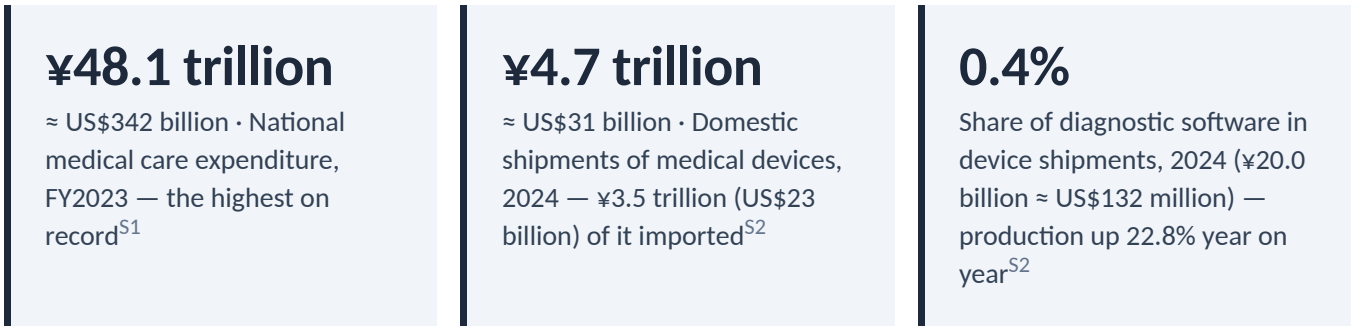
Most detours come from making these in the wrong order — typically, choosing a distributor first and discovering the evidence gap last. This paper walks through each decision, the questions that settle it, and where the road forks in a way you cannot easily reverse. It ends with what we learned taking our own AI-based software device from data design to approval, and a ten-minute way to start a conversation.

We support the process, not a guaranteed outcome. Classification, evidence requirements and reimbursement are determined product by product by the Japanese authorities.



1 Why Japan, now

A large market, and a small software slice



Japan's national medical care expenditure reached ¥48.1 trillion (about US\$342 billion) in FY2023, the highest on record^{S1 S29}. Domestic shipments of medical devices were ¥4.7 trillion (about US\$31 billion) in 2024, of which ¥3.5 trillion (US\$23 billion) were imports — Japan's device market is, and has long been, import-dependent^{S2 S29}.

Inside that market, software is still small. Diagnostic software devices (疾病診断用プログラム) shipped ¥20.0 billion (about US\$132 million) domestically in 2024 — about 0.4% of device shipments — while domestic production of the category grew 22.8% year on year^{S2}. The category is young. That is the opportunity, and the reason the rules have been rewritten around it. US dollar figures in this paper are converted at the US Federal Reserve's annual average rates (¥140.50 per US\$ for 2023; ¥151.46 per US\$ for 2024) and rounded^{S29}.

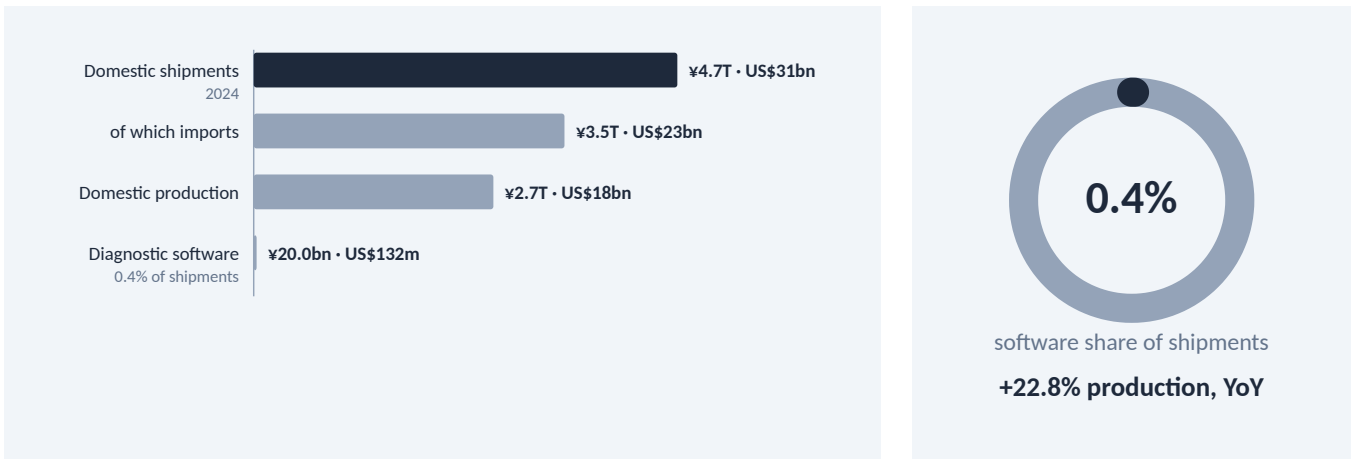


Figure 1 — Japan's medical device market, 2024. Domestic shipments ¥4.7 trillion (US\$31 billion); of which imports ¥3.5 trillion (US\$23 billion); domestic production ¥2.7 trillion (US\$18 billion); diagnostic software ¥20.0 billion (US\$132 million), 0.4% of shipments^{S2 S29}.

Five years of policy aimed at software

In November 2020 the Ministry of Health, Labour and Welfare (MHLW) published **DASH for SaMD** — "DX Action Strategies in Healthcare for Software as a Medical Device" — a package designed to speed up review of software devices. Its core measures were a single consultation window (the SaMD one-stop desk), a dedicated SaMD review office at the Pharmaceuticals and Medical Devices Agency (PMDA), and a commitment to publish review approaches early so developers could see what would be asked of them^{S3}.

In September 2023, MHLW and the Ministry of Economy, Trade and Industry (METI) jointly published **DASH for SaMD 2**. It added two things that matter directly to overseas developers: a published framework for **two-step approval** of software devices, and an explicit goal of international expansion — both attracting overseas SaMD to Japan and taking Japanese SaMD abroad^{S4 S5}. The two-step framework itself was set out in an MHLW notification of 16 November 2023^{S6}.

Alongside these, PMDA has been publishing **review points** by product type — the test conditions and evaluation points used for products approved since 2014 — and moving established categories of SaMD from approval to the faster certification route^{S7}. PMDA also maintains an official guide to SaMD development and filing, last updated in May 2026^{S8}.

The direction is clear. The rules are moving toward software, and toward predictability. What they do not do is tell you, for your product, which route applies and what evidence will be asked for. That is the map this paper tries to draw.



2 Decision 1 — Your regulatory route

The question

Is your product a medical device in Japan at all, and if so, which class and which route?

What decides it

Japan classifies devices into four classes (I–IV) by risk, broadly aligned with the international GHTF/IMDRF scheme, grouped under the PMD Act into general, controlled and specially controlled devices, and assigns one of three routes^{S8}:

- **Notification (*todokede*)** — Class I general devices.
- **Certification (*ninsho*)** — Class II, and some Class III, devices for which a certification standard exists, reviewed by a registered certification body.
- **Approval (*shonin*)** — everything else, reviewed by PMDA with the final decision by MHLW.

For software, the first question is often not the class but **applicability** — whether the intended use makes the software a medical device under the PMD Act at all. DASH for SaMD identified this as the first thing developers could not work out on their own, and it is the first thing the one-stop desk exists to answer^{S3}.

Three practical points for overseas teams:

- **Your home classification is a starting point, not an answer.** A product cleared as Class II in the US or CE-marked as IIa may land in a different class in Japan, and the route depends on whether a certification standard exists for your category. Where SaMD categories have approval precedents, MHLW has been creating certification standards to move them to the faster route^{S7}.
- **Two-step approval changes what you need at the first filing.** Under the November 2023 notification, a software device can be approved first on a narrower claim or evidence base, with a second step to expand the claim once further evidence is collected. The approach is optional — a product can still be approved in one step — and the industry association has published worked examples for diagnostic software^{S6 S9}. Whether your product fits, and what the two steps would contain, is a matter for consultation.
- **Use the one-stop desk before you design anything for Japan.** The SaMD consultation window at PMDA answers classification, development and reimbursement questions in one place, with the relevant MHLW divisions in the room^{S7}. It is the cheapest month you will spend on Japan.



Where the road forks

The intended use you file is the intended use you get. Narrowing the claim to fit the first step of a two-step approval is reversible; broadening it later requires the second step and the evidence to support it. Deciding the claim before you design the evidence is the first place companies save a year — or lose one.

The question everyone asks

"Do we need Japanese clinical data?"

The honest answer

Not automatically. Japan has accepted clinical data generated overseas as review material since 1985, provided it meets defined conditions on study conduct and reporting; the notice expressly covers medical devices^{S10}. The ICH framework on ethnic factors (E5), adopted in Japan in 1998, sets out when foreign data can be extrapolated to Japanese patients and when bridging data is needed^{S11}. Since 2017, a separate MHLW "rebalancing" notice has set out when a device application can be filed without new pre-market clinical trials at all, relying on existing and post-market evidence; the 2023 two-step notification builds on it for software^{S6}.

So the real question is narrower: **does anything about Japan change the performance or safety of your product?** For AI and software devices the answer usually turns on practice rather than physiology:

- **Input differences.** Imaging equipment, staining protocols, sample handling, laboratory workflow and data formats common in Japanese hospitals may differ from those in your training and validation data.
- **Population and prevalence.** Disease prevalence, subtypes and comparator practice can differ enough to change a diagnostic's positive predictive value in the field.
- **Reference standard.** What counts as the "correct answer" in Japanese clinical practice may not be the reference your model was validated against.

Where these differences are small or can be shown to be small, existing data may carry, sometimes with a modest Japanese confirmatory dataset. Where they are material, a Japanese study — often smaller than a full pivotal trial — is the path. **Which of these applies to your product is decided in PMDA consultation, not in this paper.**

What to bring to that consultation

- A clear description of the input data your model was trained and validated on: devices, protocols, sites, countries.
- Performance stratified by any variable that might differ in Japan.
- A proposal, not a question: "We believe our data carries because X; we propose a Japanese confirmatory dataset of Y to show Z." Regulators respond to proposals.



Where the road forks

Data you collect in Japan for one purpose is hard to reuse for another. If you may later want reimbursement (Decision 5), the endpoints that support a reimbursement case are often different from those that support approval. Design the study once, for both.



4 Decision 3 — Your clinical partner

The question

Which Japanese hospital or academic group will work with you, and what do they need before they will?

Why this is the hard one

Of the five decisions, this is the one that overseas companies most often underestimate. A Japanese hospital that participates in your study, lends a key opinion leader to your advisory board, or co-authors your paper is putting its name on your product. It will want credible data first, a clear protocol, and a Japanese counterpart it can hold accountable. Cold outreach to department heads rarely works; introductions do.

What a partner typically needs from you

- **Evidence before engagement.** Your existing performance data, in a form a clinician can read in ten minutes.
- **A protocol they can take to their ethics committee.** Japanese ethical review follows national guidelines for medical research involving human subjects; institutional review boards will expect endpoints, sample size justification, data handling and consent materials in Japanese, and a named Japanese principal investigator.
- **A local counterpart.** Someone in Japan who can attend the meetings, answer the committee's questions and manage the study day to day. This is rarely the distributor.
- **Clarity on publication and data rights.** Who can publish, when, and who owns the Japanese dataset afterwards.

Time

From first introduction to first patient enrolled, allow for the introduction, an initial scientific discussion, protocol drafting, ethics review and contracting. Ethics review alone can take several months, and the total varies widely by institution. We do not publish a typical figure, because the honest range is too wide to be useful; what we can say is that this stage, not the regulatory review, is usually the long pole.



Where the road forks

The partner you choose for the study will shape the reference standard, the endpoints and, often, the first customer. A partner chosen for convenience rather than fit is the most expensive decision to reverse, because reversing it means a second study.



5 Decision 4 — Your presence in Japan

The question

Do you need a Japanese company to sell in Japan?

The three options

You need a Japanese **marketing authorization holder** — a company holding the relevant manufacturing/marketing business licence (*seizo-hanbai-gyo kyoka*), physically located in Japan, responsible for quality (QMS) and post-market safety (GVP) — but you do not necessarily need to *be* one. The options^{S8 S12 S13}:

 A. Your own subsidiary Holds approval Your subsidiary MAH Your subsidiary — own licence, three statutory responsible persons, QMS/GVP Fits when You are committed to Japan long term and expect several products  Slowest to set up	 B. A Japanese MAH partner Holds approval The partner MAH The partner Fits when You want speed and a partner already selling to your customers  The approval is in the partner's name; changing partner later is difficult	 C. Your own approval + Designated MAH (DMAH) Holds approval You, via the Foreign Special Approval System MAH A Japanese licence holder you designate, who performs QMS/GVP duties in Japan Fits when You want to own the approval without a subsidiary  Still needs a licensed Japanese company; the DMAH must be replaced if the relationship ends
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Figure 3 — Three ways to be present in Japan.

In all three cases your manufacturing sites will need **foreign manufacturer registration** with MHLW under the PMD Act^{S14}, and your quality system will be inspected against Japan's QMS Ordinance, which is aligned with ISO 13485.

What we hold



Class II MAH licence
第二種医療機器製造
販売業許可・obtained
November 2023^{S15}



**Medical device
manufacturing licence**
Obtained January
2023^{S15}



ISO/IEC 27001:2022
Information security
management・
registered May 2024^{S16}

Together these allow us to design, develop, manufacture, file and market software medical devices up to Class II in our own name. We can act as the marketing authorization holder for a partner's device up to Class II and place it on the Japanese market.



Where the road forks

Option B is the fastest and the hardest to unwind: the approval belongs to the partner. If there is any chance you will want to change partner, own the approval (Option C) from the start.



6 Decision 5 — Your commercial route

The question

Will you seek reimbursement, and if not, who pays?

How reimbursement works for software

Japan's national health insurance reimburses medical devices through defined categories — from A1 (bundled into an existing procedure fee) through C2 (a new technology needing a new fee) — and the category rules expressly include software devices^{S17}. Since the FY2022 fee revision, software devices have had their own section in the fee schedule (the "SaMD medical management add-on"), and since June 2024 two further mechanisms have applied to SaMD: evaluation-based coverage for products with a first-step approval, and a "challenge application" route to seek re-evaluation once real-world use data accumulate^{S18 S19}. The rules are revised every two years; the latest revision took effect for FY2026^{S20}.

Three things to decide early

- **Reimbursed, or self-pay?** Reimbursement opens the whole market but adds a second review, with its own evidence expectations (clinical usefulness, often against existing practice). Some software products are sold to hospitals as operational tools outside the fee schedule.
- **Design the study for both reviews.** If reimbursement is the goal, the endpoints that support a fee are often not the endpoints that support approval. Decide before Decision 2 is finalised.
- **Who sells?** Japanese hospitals buy through dealers and wholesalers with long-standing relationships. A distributor is a channel decision, not a regulatory one — separate it from Decision 4.



Where the road forks

Reimbursement applications follow the fee revision cycle. Missing a cycle can mean a two-year wait. Work backwards from the revision calendar when you plan your submission.



7 The order matters — four sequences that fail

These are patterns we have seen, described generically.

Distributor first

A company signs a Japanese distributor, who then asks for a product that can be sold — and neither side has worked out the regulatory route or the evidence. The distributor waits; the relationship cools.

Evidence first, claim last

A Japanese study is run on the assumption that "more data is better", then the claim is defined afterwards. The study answers a question the regulator did not ask.

Approval first, reimbursement never

The product is approved, then the team discovers the reimbursement case needed different endpoints. A second study, or a self-pay strategy nobody planned.

Partner for convenience

The first hospital that says yes becomes the study site; it turns out not to be representative, and the data do not generalise. The second study is the expensive one.

The common thread: each of the five decisions was made in isolation. Decisions 3, 2 and 1 in particular need to be made together, and before Decisions 4 and 5 are locked.

8 A realistic timeline

We do not publish a predicted duration, because it depends on the product. What we can say is which activities set the pace, and that the middle three run in parallel.



Figure 4 — Six stages to market, with stages 3–5 in parallel.

PMDA publishes its own review-period targets. In our experience the review itself is rarely the long part; the time before submission is.



9 What we did ourselves

This is not a case study of a client. It is what happened when we took our own product through the process, offered because it is the basis of everything above.

BiTTE®-Urine is an AI-based software device that supports estimation of the causative bacterial species in urinary tract infection from Gram-stained microscope images captured with a smartphone. We developed it with Kobe University and the National Center for Global Health and Medicine (now the Japan Institute for Health Security, JIHS). It was approved in Japan as a **Class II software medical device** (generic name: microorganism classification support program) on 27 November 2024, approval no. 30600BZX00247000^{S21 S22}.

The sequence we followed, in the order we followed it:

- 1 **Clinical partner and data design together.** The hospital partners shaped what "correct" meant and how images would be collected, before a model existed. The training set was built from anonymised specimens collected at the two partner hospitals under their existing registries^{S23}.
- 2 **Model built on that design,** with the validation dataset planned around the claim we intended to file.
- 3 **PMDA consultation** on the claim, the evidence and the comparison to expert performance.
- 4 **Submission and approval.**
- 5 **Publication.** The comparison between the software and ten microbiology specialists, on 306 images from two tertiary hospitals using a non-inferiority design, was published in the *Journal of Medical Microbiology* in April 2025^{S23}. We cite the paper rather than restate its results here.

Figure 5 — The sequence we followed for BiTTE®-Urine.

We also run our own BSL-2 laboratory in Kobe, which allowed us to generate training data ourselves rather than wait for it^{S28}. Most overseas companies will not need that; the point is that data design, partner and claim were decided together, first.

The collaboration was recognised in April 2026, when BiTTE®-Urine received the Excellence Award in the Software category of the 38th SME Excellent New Technology and Product Awards, organised by the Resona Foundation for Small and Medium Enterprise Promotion and Nikkan Kogyo Shimibun. In the same programme our collaborator at JIHS received the Industry-Academia-Government Collaboration Special Award — the collaboration was recognised, not only the product^{S24 S25}.



10 How to start

A ten-minute intake form, then a conversation. Nothing confidential is needed; a public version of your deck is fine, and we can sign an NDA first if you prefer.

What the form asks: your company, country and stage; the product and what it is for; approvals, evidence and funding at home; what you want in Japan and by when.



1. Ten-minute intake form

Nothing confidential; a public deck is fine.



2. Online session

Our regulatory, clinical and AI people review your form together, then meet you on Japan fit and route — within a few working days.



3. Written scope and quotation

Only if it is worth going further. Nothing starts before you agree.

Start with the intake form — forms.gle/yAixX5dqgXtc3idZA

or write to us via carbgem.com/en

Contact us

If you have any questions about this document, our products and services, or our DX/AI solutions, please get in touch through our contact form.



11 About CarbGeM Inc.

CarbGeM is a technology company driving innovation across the life sciences through advanced solutions, including regulatory-approved Software as a Medical Device (SaMD). Our AI and digital platforms support diagnostic workflows, streamline research processes, and promote standardized and automated quality control across clinical, research, and industrial settings.

By addressing social challenges—such as shortages of skilled personnel and regional disparities—we help enable fast and accurate decision-making in medical and industrial environments. Our solutions span research-use AI, municipal and industrial DX, and evidence-based decision support leveraging scientific and data-driven insights.

CarbGeM has received numerous awards in Japan and abroad, including selection in the world Top 10 of the Global AI Impact Challenge at the AI Impact Summit 2026 hosted by the Government of India^{S26}, the Tokyo Social Innovation Tech Award 2024 hosted by the Tokyo Metropolitan Government^{S27}, and the Excellence Award (Software) at the 38th SME Excellent New Technology and Product Awards^{S24}. We actively advance open innovation through collaboration with industry, government, and academia to build the future of healthcare, research, and local communities.

Website: <https://carbgem.com/en/>



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Appendix — Glossary

Term	Japanese	Meaning
PMD Act	薬機法	Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices etc. — Japan's device law
MHLW	厚生労働省	Ministry of Health, Labour and Welfare — the regulator
PMDA	医薬品医療機器総合機構	Pharmaceuticals and Medical Devices Agency — the reviewer and consultation body
Shonin	承認	Approval by MHLW after PMDA review
Ninsho	認証	Certification by a registered certification body against a standard
Todokede	届出	Notification, for Class I devices
SaMD	プログラム医療機器	Software as a Medical Device
MAH	製造販売業者	Marketing Authorization Holder — the licensed Japanese company responsible for the product
DMAH	選任製造販売業者	Designated MAH — a Japanese licence holder designated by a foreign approval holder
FSAS	外国特例承認制度	Foreign Special Approval System — lets a foreign company hold approval in its own name with a DMAH
FMR	外国製造業者登録	Foreign Manufacturer Registration with MHLW
QMS Ordinance	QMS省令	Japan's quality management system requirements, aligned with ISO 13485
GVP	GVP省令	Good Vigilance Practice — post-market safety requirements
Chuikyo	中医協	Central Social Insurance Medical Council — sets reimbursement

Disclaimer. This paper is general information, not regulatory, legal or reimbursement advice for any specific product. Classification, evidence requirements, approval and reimbursement are determined by the Japanese authorities product by product. CarbGeM supports the process and does not guarantee any outcome. AI Studio models are for research use only. Nothing here is an offer; scope and fees are agreed in writing.

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