

THE INDIA LOCALIZATION GUIDE

70–80%

of India's medical
devices are imported.

**Not because we cannot build them.
Because almost nobody re-engineers them properly.**

The 8-page decision guide for Indian medical device manufacturers — what to localize, what to leave, and the five traps that kill the projects that fail.



The whole guide, on one page.

Six questions. Answer all six and you are ready to localize. Fail three of them and you are about to lose two years.

1 Should you make this at all?

There are **five valid answers** — make fully, make deeply, assemble, license, or walk away. Most companies never choose. They drift into assembly and call it manufacturing.

2 How much of it is actually Indian?

Not part count. Not labour. **Share of BOM value**. This is the one number PLI audits and tender committees test — and most "Made in India" devices fail it.

3 Which functions have no Indian source?

There are always one or two. Naming them honestly on day one is the difference between a plan and a disappointment.

4 Whose patent are you about to walk into?

Never copy the imported device. **Decompose it into functions** and engineer to the requirement.

5 Can you actually win?

Sometimes the honest answer is no. A Chinese plant at 400,000 units will always out-cost you at 5,000. **Then win on what they cannot copy.**

6 What breaks first?

Five traps have killed real Indian programmes. They are predictable — which means they are avoidable.

The most valuable thing this guide can do for you

Save you two years. A clear, evidenced "no" delivered in six weeks is worth far more than a hopeful "yes" that collapses in month twenty-two.



— THE NUMBER THAT DECIDES EVERYTHING

"Made in India" is a number, not a sticker.



Localization Depth — the share of your bill-of-materials value that is genuinely Indian.

Two devices. Same factory. Same claim on the box.

DEVICE A • CLAIMS "MADE IN INDIA"

22%

domestic value addition

78% still lands at Chennai port. The sensor, the pump head and the driver IC are all imported. The enclosure and the assembly labour are Indian.

A kit with a sticker — and the PLI auditor will use exactly those words.

DEVICE B • SAME PRODUCT, RE-ENGINEERED

81%

domestic value addition

Only the sensor is still imported. The compressor was localized. The oxygen cell was designed out entirely and replaced with a sensor that has no consumable at all.

Clears PLI and the tender local-content clause. Device A never will.

THE LOCALIZATION DEPTH SCALE

<35%

ASSEMBLY

Do not claim otherwise

35–50%

PARTIAL

Fails a serious test

50–65%

GENUINE

A real Make-in-India device

65%+

DEFENSIBLE

A manufacturing asset

Why this number is worth money

An imported unit structurally cannot meet a local-content clause, however cheap it is. That is not a cost advantage — it is a **market-access advantage**. A door the incumbent cannot walk through, and you can.

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SCAN TO
EXPLORE

Five valid answers. Most companies never choose.

Localization is a decision, not a default. Pick one, write it down, and fund it properly.

1 Make it fully

18-36 MONTHS

When: high value · thin global scale · Indian supply exists for most functions · strong tender pull.
You get: maximum domestic value, PLI, full margin. **It costs:** the longest path — supplier development, not just sourcing.

2 Make it deeply

9-18 MONTHS

When: one or two functions genuinely have no Indian source — everything else can be made here.
You get: most of the benefit for a fraction of the pain. **It costs:** the discipline to say out loud which parts you will keep importing.

USUALLY THE RIGHT ANSWER

3 Assemble here

3-6 MONTHS

When: you need a market presence fast · the device is commoditised. **You get:** speed, a local address, a foot in the door. **It costs:** do not call this Make in India. Legitimate as Phase 1 — only with a written plan to exit it.

4 License it

6-12 MONTHS

When: the core function sits inside a patent fortress and no design-around meets the spec. **You get:** legal certainty and a proven product. **It costs:** a royalty forever, and a ceiling on your margin. Sometimes the honest answer.

5 Walk away

DECIDE IN 6 WEEKS

When: a global player has 20×+ your scale on a true commodity, or the market cannot fund the development. **You get:** the two years you were about to lose. **It costs:** only your ego.

A WIN, NOT A FAILURE



Every one of these has killed a real Indian programme.

They are predictable — which means they are avoidable.

TRAP 01

The consumable trap

You localize the machine and keep importing the part that dies every twelve months. You did not remove an import — you turned it into a permanent annuity, paid to somebody else, forever.

THE FIX

Localize the consumable first — or design it out entirely.

TRAP 02

The "assembled in India" trap

You import the expensive 78%, screw it together here, and call it Make in India. Then the audit arrives, the value-addition is computed properly, and the PLI claim fails.

THE FIX

Compute your Localization Depth before you make the claim — not after.

TRAP 03

The patent fortress

You attack the one function the incumbent has spent thirty years fencing off. These are not accidents of engineering — they are defended moats, and exactly where a new entrant instinctively aims.

THE FIX

Go around, not through. The physics is public domain — only the implementation is claimed.

TRAP 04

The scale trap

A plant making 400,000 units a year has a bill of materials you cannot match at 5,000. That is arithmetic, not effort. No amount of Indian engineering brilliance closes a 30× volume gap.

THE FIX

Compete where scale does not decide — local content, ruggedisation, service, lead time. Or pick a different device.

TRAP 05 · THE EXPENSIVE ONE

The requirements trap

You copy the import's specification instead of the customer's requirement. It has Wi-Fi and a touchscreen, so you add both. The touchscreen does not work with gloves. The Wi-Fi drags you into cybersecurity regulation. The district hospital wanted neither — and would not pay for either.

THE FIX

Start from the standard and the customer — never the competitor's feature list. Routinely worth **15–25% of the bill of materials**.



Never copy. Decompose.

Copying an implementation is infringement. **Engineering to a requirement is competition.**

- ✗ Do NOT open the imported device**
Do not copy the BOM. Do not reverse-engineer the board. It feels efficient. It is the most dangerous thing you can do — and it is completely unnecessary.
- 1 Ask what it must DO**
Derive it from **the standard and the customer** — never from the competitor.
- 2 Decompose into functions with measurable specs**
"Deliver 0.1–1200 mL/h at $\pm 5\%$." Not "have a pump."
- 3 Enumerate every route that achieves each function**
There are always several — usually four or five. Nobody owns physics.
- 4 Flag which routes sit inside live patent claims**
And which rest on long-expired, public-domain art.
- 5 Choose a free route that meets the same requirement**
Record why you rejected the others. You now have a design that is **IP-safe by construction** — and an auditable record that proves it.

ONE FUNCTION • FOUR ROUTES		Detect an occlusion within 2 s at 300 mmHg
Strain-gauge force sensor on the plunger		₹1,100
Motor-current sensing — no sensor at all	LOWEST	₹150
In-line disposable pressure sensor		₹900
Optical deflection of the plunger flange		₹600

A ₹950 spread on a single function — and not one of these requires you to look inside anybody's product.



Are you ready to localize?

Tick the box only if you can answer with a confident yes. **12 questions · 1 point each.** The point is not to score well — it is to find out where you actually are.

- | | |
|--|---|
| ☐ 01 We have written the device's functions and measurable specs — derived from the standard, not the competitor's brochure. | ☐ 02 For every function, we know the landed cost of the component that delivers it. |
| ☐ 03 We have assigned a supply tier to every function — and been honest about the ones with no Indian source. | ☐ 04 We know our Localization Depth — the share of BOM value that is genuinely Indian. |
| ☐ 05 We know which functions carry live patent exposure, and we have mapped an alternative route for each. | ☐ 06 We know our CDSCO risk class and the licence pathway. |
| ☐ 07 Our volume assumption is based on a route to market we actually possess — not a forecast. | ☐ 08 We have identified the consumables and spares, and confirmed they can be made in India. |
| ☐ 09 We have decided which of the five archetypes we are pursuing — and written it down. | ☐ 10 We have a supplier-development plan — not just a sourcing plan. |
| ☐ 11 We have budgeted for verification, validation and testing — routinely 25–40% of development cost. | ☐ 12 We know what we will do if the honest answer turns out to be "do not localize." |

10–12

Ready. Start the engineering.

7–9

Gaps known and closable. Fix before you commit capital.

4–6

Real risk of building the wrong thing.

0–3

Stop. Not enough to decide. That is useful to know.



— WHAT TO DO NEXT

Find out in 20 minutes what usually takes two weeks.



STEP 1

Run the Engine

Twenty minutes, in your browser.
Nothing leaves your machine.

FREE · NO CALL REQUIRED

STEP 2

Book a StartSmart call

Sixty minutes with an engineer —
not a salesperson. No deck. We tell
you straight whether the device is
worth attacking.

FREE · IF WE THINK YOU
SHOULDN'T, WE'LL SAY SO

STEP 3

Localization Sprint

Bring us one imported device. BOM
teardown, qualified Indian suppliers,
design-around engineering, CDSCO
path.

FIXED SCOPE · PAID PILOT

— FREE · IN YOUR BROWSER · NOTHING UPLOADED

The Localization Engine

Pick an imported device. The engine decomposes it into functions, shows every engineering route, flags patent exposure, and tells you which functions have a real Indian supplier — and which have none at all.

- **Localization Depth** — how Indian it really is
- **Supply Reality** — what has no Indian source
- **Your next 3 moves** — ranked by value removed
- **Design Freedom** — clear of live patent claims?
- **Price umbrella** — the room you actually have
- **Design Freedom Dossier** — take it to your attorney

Three findings, or the scan is free.

Our diagnostic pilots return at least three actionable findings on your real device — or it costs you nothing.

[Start the Engine →](#)

Important. General engineering and commercial information — not legal or regulatory advice. Patent observations are indicative engineering judgement and are not a freedom-to-operate opinion; obtain one from a qualified patent attorney before commercial launch. Cost figures are indicative, order-of-magnitude and volume-dependent. Verify the current CDSCO position for your device class.

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