

# Strategic India Market Entry — Swedish Orthopaedic Medical Device Company

Regulatory recovery, clinical validation with a leading Indian institution, and a commercial launch — in under 14 months.

<b>14</b> MONTHS TO FIRST SALE	<b>14 wks</b> CDSCO CLEARANCE	<b>24</b> CLINICAL CASES VALIDATED	<b>Tier-1</b> HOSPITAL ENDORSEMENT	<b>€0</b> ENTITY SETUP COST
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## 01 · CLIENT SITUATION

### Strong product. Stalled India entry.

- 30-year orthopaedic engineering heritage — precision joint reconstruction system with superior European clinical outcomes
- CDSCO Class C registration stalled for 18 months — deficiency notice unresolved by prior agent
- No India clinical validation — CE marking and FDA clearance insufficient for Indian hospital procurement
- No active India presence — distribution architecture and go-to-market undefined
- European pricing misaligned with CGHS reimbursement and private hospital procurement norms

## 02 · BEDFORD'S APPROACH

### Regulatory to commercial — in sequence.

- Audited the deficient CDSCO filing — identified three technical omissions and restructured the authorised representative entity
- Resubmitted the corrected Class C application under MDR 2017 — zero further deficiency notices
- CDSCO Class C Import Licence secured — 14 weeks from engagement
- Introduced the client to a nationally prominent orthopaedic institution via Bedford's existing relationship network
- Structured a 24-case Product Evaluation Programme — generating an India clinical outcomes dataset for hospital tender use
- Secured a formal Letter of Clinical Support from the lead institution, covering 14 hospital facilities
- Built India-specific tiered pricing across CGHS, insurance, and private-pay segments
- Delivered a 60-page India Commercial Playbook — transferred in full to the client at engagement close

## 03 · IMPACT OF BEDFORD CONSULTS

### From stalled filing to commercial launch — 14 months.

**14 wks**

**Regulatory Resolved**  
18-month CDSCO stall cleared

**24**

**Cases Validated**  
India clinical dataset produced

**14**

**Facilities Endorsed**  
Tier-1 hospital group support

**€0**

**Entity Cost**  
Full market access — no subsidiary

“Bedford resolved our regulatory situation in 14 weeks, secured an endorsement from one of India's most respected orthopaedic institutions, and handed us a commercial playbook we could execute immediately. India is now our fastest-growing international market.”

— Chief Commercial Officer · Swedish Orthopaedic Medical Device Company