

Clinical & Regulatory Affairs

Medicos Hirata Inc.

Business Licenses under the PAL(Pharmaceutical Affairs Law)

- Type 1 Marketing Authorization Holder
- Sales licenses for “Specially Controlled Medical Devices” (11 sites)
- Manufacturing license for general device, and labeling and packaging

Medical Device Track record

- **Medical Device Track record (Shonin Approvals)**

Total 346

- Newly 125

- Partial Change 171

- Notification 50

- **Clinical trial (including Coronary Stents,
Vascular Grafts, Endovascular Graft) 5**

- **Post Market Surveillance 4**

- **Medical Device Reimbursement Total >100**

- Newly Approval 6

- Notification >100

MH's SHONIN Holder Experience

	Classification	Number of ITEMS
Harder ↑	Class IV	39
	Class III	27
	Class II	59
Easier ↓	Class I	50
	Total	175 items