



Government of Telangana
Drugs Control Administration



FORM MD-5

[See sub-rule (4) of rule 20 and sub-rule (6) of rule 20]
Licence to Manufacture for Sale or for Distribution of Class A or Class B medical device

Licence Number: **MFG/MD/2026/000248**

1. **M/s Bharath Healthcare Laboratories Pvt. Ltd., PLOT NO. 50/A, RAGHAVENDRA NAGAR COLONY, JEEDIMETLA. SUCHITRA, Hyderabad, Medchal-Malkajgiri, Telangana (India) - 500055 Telephone No.:** [REDACTED] has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at **M/s Bharath Healthcare Laboratories Private Limited, Plot No. 50/A, Raghavendra Nagar Colony, Suchitra, Hyderabad, Medchal-Malkajgiri, Telangana (India) - 500055 Telephone No.:** [REDACTED]
2. Details of medical device(s) [Annexed]

3. This licence is subject to the provisions of the Medical Devices Rules, 2017 and conditions prescribed therein.

ANNEXURE

S.No.	Details Of Device(s)
1	Generic Name : Developmental Support Software (Non-Diagnostic) Model No. : PinnacleAI GPT-OS v1.0.0 - Cloud-based SaMD. Web + Mobile (Android/iOS). ISO 13485:2016 QMS. ISO/IEC 27001:2022 ISMS. AES-256 encryption at rest. TLS 1.3 in transit. DPDP Act 2023 compliant. UDI-DI: BHCL-GPTOS-SB1-001 Intended Use : The software is intended to assist parents, therapists, educators, and caregivers by providing developmental ability measurement, readiness tracking, progress forecasting, and adaptive therapy-plan support for children aged 0-12 years. Class of medical device : Class B Material of construction : Software – Cloud-based SaaS application Dimension(if any) : Not Applicable – Software Shelflife : NIL Sterile or Non sterile : Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999) : PinnacleAI GPT-OS™

State Licensing Authority

Place:Hyderabad
Date:21-04-2026

Joint Director
Licensing & Controlling Authority
Drugs Control Administration
Hyderabad, Telangana State