

APPLICATION FOR RISK CLASSIFICATION OF MEDICAL DEVICES

Application No:MD/classification/2025/150

1. Name of applicant:

Bharath Healthcare Laboratories Pvt. Ltd.
2. Address for correspondence:

PLOT NO 50/A, RAGHAVENDRA NAGAR COLONY,
JEEDIMETLA. SUCHITRA, ,Hyderabad,Medchal-
Malkajgiri,Telangana - 500055,India
3. E-mail ID:
- 4.Name of Contact person and Contact number:

5. Product Details

S.NO	Device Details
1. 2. 3. 4.	Name of the device (Generic name) :Developmental Support Software (Non-Diagnostic) Device Category :Software Intended Use (as per the label claims) :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 Proposed risk Classification (as per the First Schedule (Part I) of the MDR, 2017) :Class A (non-sterile and non-measuring)

6. I undertake that the information provided herein is true and correct to the best of my knowledge.

Place:

Signature

Date: 08-Jan-26

(Name and Designation)