

NATIONAL MEDICAL PRODUCTS ADMINISTRATION
ANNOUNCEMENT No. 58 (2026)

**REVISED CLASSIFICATION GUIDANCE FOR ARTIFICIAL INTELLIGENCE
MEDICAL DEVICE SOFTWARE**

Issued: 25 July 2026 Effective: 25 October 2026

1. PURPOSE

This Announcement revises the 2021 classification guidance for AI-enabled medical device software (NMPA Announcement No. 47, 2021). It introduces a three-tier sub-category structure reflecting the expanded range of AI architectures now encountered in regulated products, including large language model-based clinical decision support systems.

2. DEVICE SUB-CATEGORIES

Sub-Category 1: AI Decision Support Software

Classification: Class II (advisory output only; no autonomous therapeutic recommendation; clinician retains full decision authority).

Sub-Category 2: AI Diagnostic Software

Classification: Class II or Class III depending on clinical risk matrix (see Annex I). Factors assessed: disease severity, reversibility of harm, clinical override availability, intended user qualification.

Sub-Category 3: AI Autonomous Intervention Software

Classification: Class III (includes AI-controlled drug delivery systems, autonomous radiotherapy planning, and closed-loop physiological control).

3. CLASS II / CLASS III BOUNDARY — AI DIAGNOSTIC SOFTWARE

The binary advisory/conclusive boundary in the 2021 guidance is replaced with a clinical-risk matrix (Annex I). The matrix assesses:

- a) Disease severity (mild/moderate/severe/life-threatening)
- b) Reversibility of harm if output acted upon incorrectly
- c) Availability of independent clinical override mechanisms
- d) Intended user qualification level (specialist/general/layperson)

Combinations scoring above the threshold defined in Annex I result in Class III classification irrespective of whether the software output is labelled as advisory or conclusive.

4. TRANSITION ARRANGEMENTS

Manufacturers holding existing registration certificates for AI medical device software have 18 months from this Announcement to:

- (1) Assess whether their product falls under a revised sub-category
- (2) If reclassification is required, submit a voluntary reclassification application to NMPA
- (3) Update technical documentation to reflect the new sub-category

Reclassification applications will not require full re-evaluation of previously accepted clinical evidence where the evidence base is unchanged.

5. EFFECTIVE DATE

This Announcement takes effect on 25 October 2026.