

Medical AI at Risk

Members of European Parliament have a decision to make that will fundamentally shape how artificial intelligence (AI) is governed in European healthcare. The [Internal Market and Consumer Protection \(IMCO\)](#) and [Civil Liberties, Justice and Home Affairs \(LIBE\)](#) compromise amendments propose to delete Annex I, Section A of the Artificial Intelligence Act and shift medical devices into Annex I, Section B. If adopted, AI medical devices would remain labelled as “high-risk”, but would no longer be subject to meaningful high-risk obligations.

While these proposed amendments would leave medical AI labelled as ‘high-risk’, they also strip away the safeguards that give that label meaning. In healthcare, where AI already influences diagnosis and treatment of patients, this creates a dangerous regulatory gap. Shifting these systems out of the core regime of the AI Act and into sectoral law does not simplify the framework: it delays safeguards, creates legal uncertainty, and risks undermining trust in AI while it is already deployed in clinical practice.

This policy brief, written with AI experts Hannah van Kolfschooten and Barry Solaiman, lays out the four key reasons why it is essential to keep AI medical devices within the core high-risk regime of the AI Act. [Read it here](#) (in PDF).