

Follow-up on “legacy” high-risk AI systems under the EU AI Act

QUESTION:

I have an AI-enabled algorithm in my pipeline which would be Class IIa MDSW.
 By when do I need to place it on the market to avoid Conformity Assessment under the EU AI Act?

ANSWER:

Basically, it depends on how you interpret Recital (177), Article 111(2), and Article 113(c) of the EU AI Act.

AI-enabled Class IIa (and above) MDSW	BSI’s interpretation	Decomplic’ interpretation
Does NOT need Conformity Assessment under the EU AI Act	<ul style="list-style-type: none"> If already placed on the market <u>prior to 2-Aug 2027</u>, and no significant changes are brought after that date. 	<ul style="list-style-type: none"> If already placed on the market <u>prior to 2-Aug-2026</u>, and no significant changes are brought after that date.
NEEDS Conformity Assessment under the EU AI Act	<ul style="list-style-type: none"> Any new applications after 2-Aug-2027. If already placed on the market <u>prior to 2-Aug 2027</u>, and significant changes are brought after that date (in this case, reassessment under the EU AI Act is needed). 	<ul style="list-style-type: none"> Any new applications after 2-Aug-2027. If already placed on the market <u>prior to 2-Aug-2026</u>, and significant changes are brought after that date.

In brief, whereas a "legacy" status for high-risk AI systems is possible, we will have to wait for further clarification from the European Commission or Competent Authorities on the scope and timelines that apply.

BACKGROUND:

Recital (177) of the EU AI Act reads:
"In order to ensure legal certainty, ensure an appropriate adaptation period for operators and avoid disruption to the market, including by ensuring continuity of the use of AI systems, it is appropriate that this Regulation applies to the high-risk AI systems that have been placed on the market or put into service before the general date of application thereof, only if, from that date, those systems are subject to significant changes in their design or intended purpose. It is appropriate to clarify that, in this respect, the concept of significant change should be understood as equivalent in substance to the notion of substantial modification, which is used with regard only to high-risk AI systems pursuant to this Regulation. On an exceptional basis and in light of public accountability, operators of AI systems which are components of the large-scale IT systems established by the legal acts listed in an annex to this Regulation and operators of high-risk AI systems that are intended to be used by public authorities should, respectively, take the necessary steps to comply with the requirements of this Regulation by end of 2030 and by 2 August 2030."

- The "general date of application" is 2-Aug-2026. However, the EU AI Act shall be implemented in a staggered manner, with some deadlines happening before and some after this date.

Then, **Article 111(2)** specifies that:

"Without prejudice to the application of Article 5 as referred to in Article 113(3), point (a), this Regulation shall apply to operators of high-risk AI systems, other than the systems referred to in paragraph 1 of this Article, that have been placed on the market or put into service before 2 August 2026, only if, as from that date, those systems are subject to significant changes in their designs. In any case, the providers and deployers of high-risk AI systems intended to be used by public authorities shall take the necessary steps to comply with the requirements and obligations of this Regulation by 2 August 2030."

- EU AI Act Art. 5 concerns prohibited AI practices.
- "Operators" are defined in EU AI Act Art. 2(8) as the provider, product manufacturer, deployer, authorised representative, importer or distributor.
- For providers of high-risk AI systems, Art. 16 summarizes the requirements, which include, among others, conformity assessment under the EU AI Act.

Last, **Article 113(c)** indicates that:

"Article 6(1) and the corresponding obligations in this Regulation shall apply from 2 August 2027."

- Art. 6(1) concerns high-risk AI systems that are safety components or products governed by EU legislation listed in Annex I (it includes EU MDR and IVDR) and require a Notified Body for the conformity assessment under such EU legislation. Basically, this article would exclude AI-enabled MDSW that is Class I (EU MDR) or Class A (IVDR).
- High-risk AI systems are also possible under Article 6(2) conditions (i.e. products with purposes listed in Annex III). There is no specific reference to this article in the transitional provisions, thus, the EU AI Act would apply to them from the general date of application, 2-Aug-2026.

For a **more detailed interpretation**

- BSI considers that Art.6(1) (which includes the definition of high-risk AI systems that would concern medical devices of Class IIa and above or Class B IVDs and above) will not be applicable on 2-Aug-2026, per Art. 113(c), as Art.6(1) has application date of 2-Aug-2027. Thus, AI-enabled medical devices do not become high-risk systems until 2-Aug-2027. Consequently, Art 111(2) is only applicable for high-risk AI systems with application date of 2-Aug-2026, i.e. those according to Art. 6(2), and all high-risk AI systems according to Art. 6(1) will need to undergo Conformity Assessment under the EU AI Act from 2-Aug-2027. Specific for "legacy" AI enabled MD systems (Class IIa and above, high-risk under EU AI Act), placed on the market prior to Aug 2027, any significant change applied following that date will need to be assessed under EU AI Act.
- Decomplicx considers that the legislator's intention, as expressed in Recital (177), is to allow "legacy" status for all high-risk AI systems under the EU AI Act. In addition, it considers that Art. 111(2) applies to all high-risk AI systems (i.e. both per Art. 6(1) and Art.6(2)) and that the cut-off date of 2-Aug-2026 for a "legacy" status makes sense as it is the general application date, irrespective of the fact that Art.6(1) would only apply from 2-Aug-2027 to high-risk AI systems. Consequently, high-risk AI systems according to Art. 6(1) will need to undergo Conformity Assessment under the EU AI Act from 2-Aug-2027 except if they had been placed on the market prior to 2-Aug-2026 and no significant changes are brought to them.