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5-minute guide:

EN 18286 | What's new & what's the impact?

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Last month (July 2026), CEN & CENELEC published the European Standard EN 18286, which defines a QMS specifically to meet Article 17 of the EU AI Act.

In this 5-minute guide, our Head of Regulatory Richie Christian recaps the context behind this standard, expands on what EN 18286 requires, and outlines the potential impact for manufacturers of AI-enabled medical devices...

The context

A bit of background

The EU AI Act regulates how AI systems are developed, placed on the market, put into service, and used within the European Union. Under the Act, providers of high-risk AI systems (HRAI) have several obligations to meet. One of those obligations is putting a QMS in place as per Article 17.

Being a regulation under the new legislative framework, compliance with harmonised standards provides presumption of conformity with essential requirements. Harmonised standards are one of the cornerstones of effective implementation of the AI Act.

Following the EU Commission’s submission of a standardisation request to develop harmonised standards for the AI Act, the CEN-CENELEC Joint Technical Committee 21 (JTC 21) has been undertaking standardisation work since May 2023.

The latest

The publishing of EN 18286

In July 2026, CEN & CENELEC published the European Standard EN 18286, which defines a QMS specifically to meet Article 17 of the EU AI Act.

It specifies comprehensive elements for an AI-centric QMS, including but not limited to regulatory compliance, risk management, product realisation, and management responsibility.

The standard is expected to be published in the Official Journal of the EU at which point it will become a harmonised standard under the AI Act.

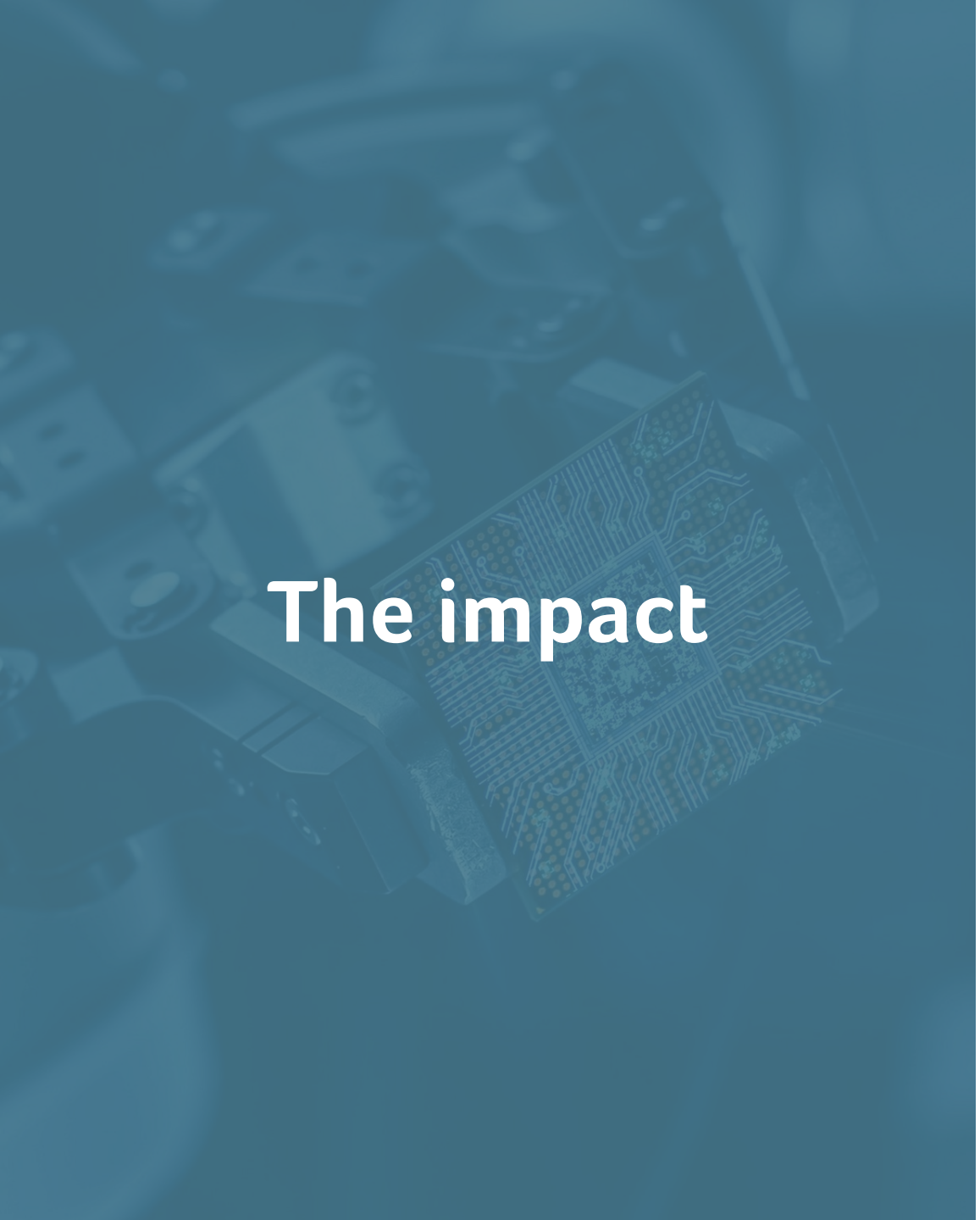
EN 18286 vs ISO 42001

EN 18286 is specifically created to implement the Article 17 QMS regulatory requirements for providers of HRAIs under the AI Act.

ISO 42001 is a general AI management system (AIMS) standard that provides a framework for organisations to responsibly develop, deploy, and govern artificial intelligence systems, to manage AI risks.

Implementation of ISO 42001 is voluntary. The standard cannot be used to demonstrate regulatory compliance with either the AI Act or MDR/IVDR.

Both are management system standards and overlap in some respects, but their intended purposes in a regulatory context are different.

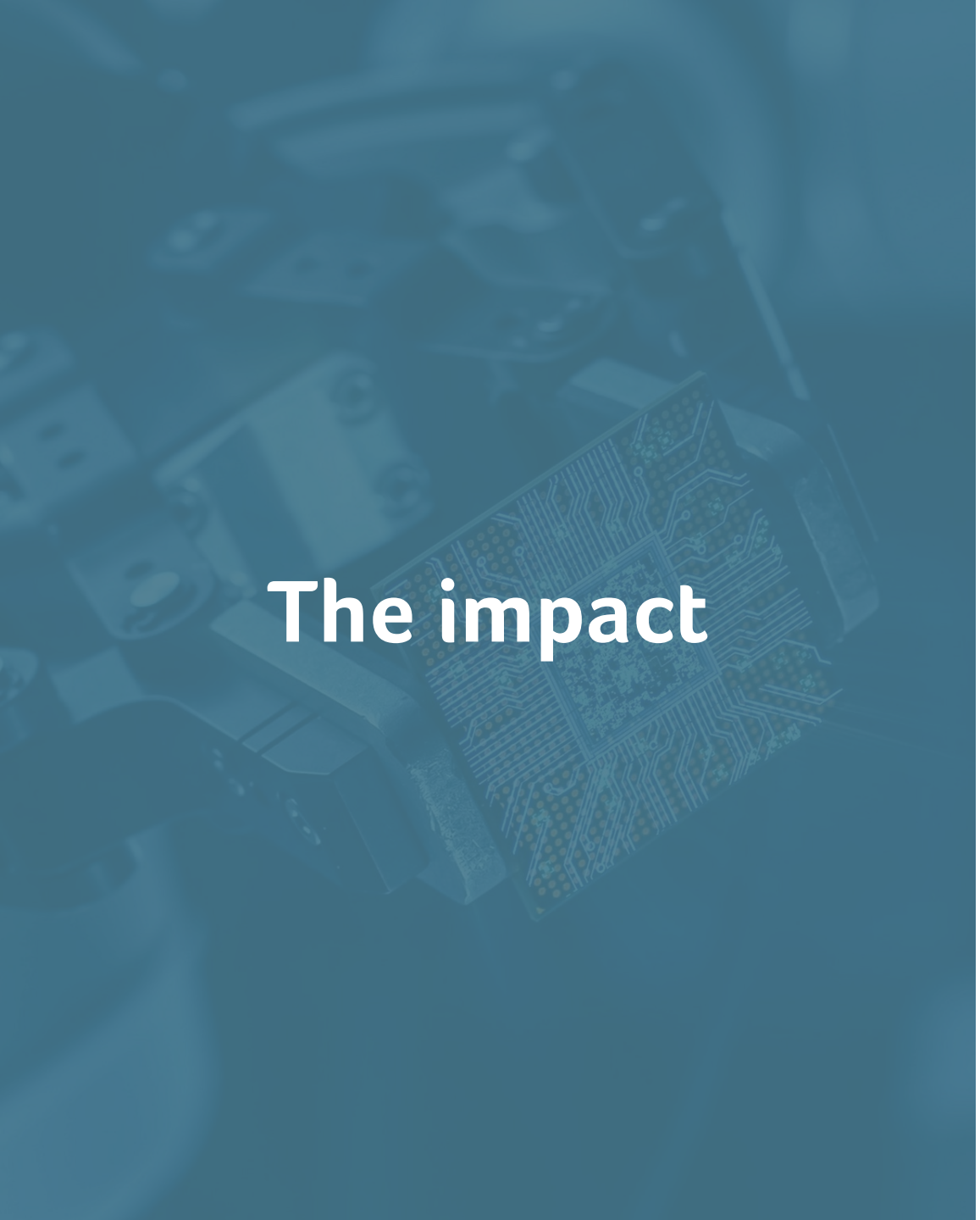


The impact

How will EN 18286 affect requirements?

The impact of EN 18286 depends on the MDR/IVDR simplification proposal (MDR/IVDR 2.0), and specifically, the proposal to move MDR/IVDR references from Section A to B in Annex III of the AI Act.

If the proposal is accepted:	If the proposal is rejected:
✓ EN 18286 may be considered state-of-art by Notified Bodies (in the absence of another European Standard for AI medical devices)	✗ Manufacturers will be required to meet full HRAI provider obligations, including implementing Article 17 QMS requirements via EN 18286



The impact

How will EN 18286 affect requirements?

Regardless of the MDR/IVDR 2.0 simplification outcome for the AI Act, **prudent manufacturers should review EN 18286 and prepare to implement additional requirements within their existing MDR/IVDR QMS.**

We recommend building adequate AI QMS capability now rather than waiting on legislative uncertainty to be resolved.

Should you require regulatory support regarding your medical device, contact our experts today.

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