## Questions and Answers from the Webinar

**Will the webinar be recorded and shared afterward?**
*Yes, you can watch or rewatch the webinar here: https://www.ds.dk/en/news/2024/ai-act-and-the-future-standards*

**I'm guessing we'll come to the harmonized standards, and which are currently being worked on, but what about Guidance? In the medical device industry, we have the MDCG who publishes amendments, interpretations (clarifications) and guidance documents - will there be something similar for the AI Act?**
*Indeed, standards can to a large degree support this purpose and give guidance, however, this is still a work in progress.*

**As a matter of general interest, is regulation for AI being prepared by other nations/regulatory-authorities outside the EU?**
*Yes, but the AI Act is the world's first AI regulation.*

**In the absence of standards at least until 2025 and high-risk AI requirements being applicable already in 2026/2027, what can we as MFG currently do as prep? any tips/suggestions or standards to look into?Asking as a Medical device MFG**

*Yes, you can find guidance in the ISO/IEC standards, however, they will not ensure presumption of conformity with the AI Act. See this link for more info:*
https://www.iso.org/committee/6794475/x/catalogue/p/1/u/0/w/0/d/0

**You ask about standards and says in absence off - What about the ISO 42001 and the use of a AI Management system?**
*ISO 42001 will not provide presumption of conformity, but a homegrown European standard will be developed based on ISO 42001. This future standard will be harmonised and give you presumption of conformity.*

**Do the standardization bodies already exclude certain programming approaches/ methods from the scope of the standards they are working on for e.g. well-established statistical methods? or are they waiting for the guidance on the definition of AI system?**
*The creation of the standards is currently in progress, and we cannot yet comment on their specifics. We aim to publish them in 2025 or 2026 and we encourage everyone to join their national standardisation body if they would like early insight and participating in developing them.*

**Would the standards under approval on your slide be approved in 4 parts?**
*The standards are being developed as fast as possible in close collaboration with the European Commission, who will assess how they live up to the criteria in the AI Act. Each standard will be subject to public enquiry among the member countries and approved as four separate projects.*

**How will fundamental rights be reflected in the standards (e.g. risk management, bias, transparency, etc.)?**
*Ensuring fundamental rights is a core principle in the AI Act. The European Commission, who will assess every harmonised standard to ensure just that. Also, standardisation is a consensus process, where there is a large number of European experts and organisations involved in creating the standards, and fundamental rights are being taken into the development. This ensures expertise on societal issues.*

**If the standards are published in the Official Journal of the EU, does this mean that these standards be publicly available (for free), or do organizations have to purchase them?**

| |
|---|
| *We do not know yet, if the standards will become publicly available or whether they must be purchased.* |
| **Is there any collaboration between CEN/CLC/JTC21 and the ETSI TC SAI (Securing Artificial Intelligence)? ETSI is not part of the standardization request (SR) but can standards developed by ETSI be listed in the OJEU in the end (even though they are outside of the SR)?**<br>*Yes, ETSI and CEN-CENELEC have a formal cooperation and ETSI experts can join JTC 21 Working Groups. The current Standardisation REquest does not allow ETSI standards to be harmnonised and listed in the OJEU.* |
| |