



**Sony's mSafety says,
"Yes, you can."**

**Using Aligned Elements to support
ISO 13485 and IEC 62304**

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SONY

The Company

Created by Sony Network Communications Europe, [mSafety](#) is a secure and reliable platform for mobile health and safety applications. It combines a user-friendly wearable that collects and displays data with a solid back-end solution.

The mSafety platform allows companies to build precisely targeted remote monitoring services that address specific customer needs. There are many competitors in this field making product differentiation and ease of adoption vital.

A major differentiator and competitive advantage is preparing this platform to be ready to fulfill medical regulatory standards, such as IEC 62304 and ISO 13485, in order to facilitate for customers to certify medical applications they build on mSafety. In doing this, the mSafety platform has lowered the barriers in making that happen. Why did they choose Aligned Elements?

The Challenge

"We investigated the relevant standards and made decisions on the level of compliance we needed," says Claes Nilsson, Master System Engineer at Sony Network Communications Europe. "We then looked for a tool specially designed for the quality and lifecycle requirements defined by the relevant standards that could facilitate the creation of documentation and lifecycle management."

Based on recommendations from a trusted source, Aligned Elements was selected as the right tool to use. Aligned Elements also supported the direction that Sony needed to get to in terms of quality of documentation. "That was the major reason we chose Aligned", mentioned Claes.



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The Solution



After a trial period Sony chose to move forward with Aligned Elements to achieve their adherence to these critical safety standards. The next challenge was to learn the tool well enough to make it a seamless part of their team's daily life. Claes admits that there was some learning time needed, but this was offset by the ease of adding requirements and creating output documents and Aligned's great support. "AE supports a structured way to, starting from requirements, create a traceable set of documentation through the whole lifecycle", says Claes.

For more information about Aligned Elements, please visit our website at www.aligned.ch

Aligned Elements and Medical Device Standards

Aligned Elements and ISO 13485

Aligned Elements provides Design Control management for design and development inputs & output, reviews, verification and validation activities as required by ISO 13485:2016 section 7.2 and 7.3. These design controls used in Documents managed by Aligned Elements in accordance with ISO 13485:2016 section 4.2.3 and 4.2.4.

Aligned Elements and IEC 62304

Aligned Elements provides capturing, versioning and tracing of Design Controls listed in IEC 62304. It facilitates a connection between the device's risk assessment and the software architecture items in order to control and evaluate Software Safety Classification values automatically.