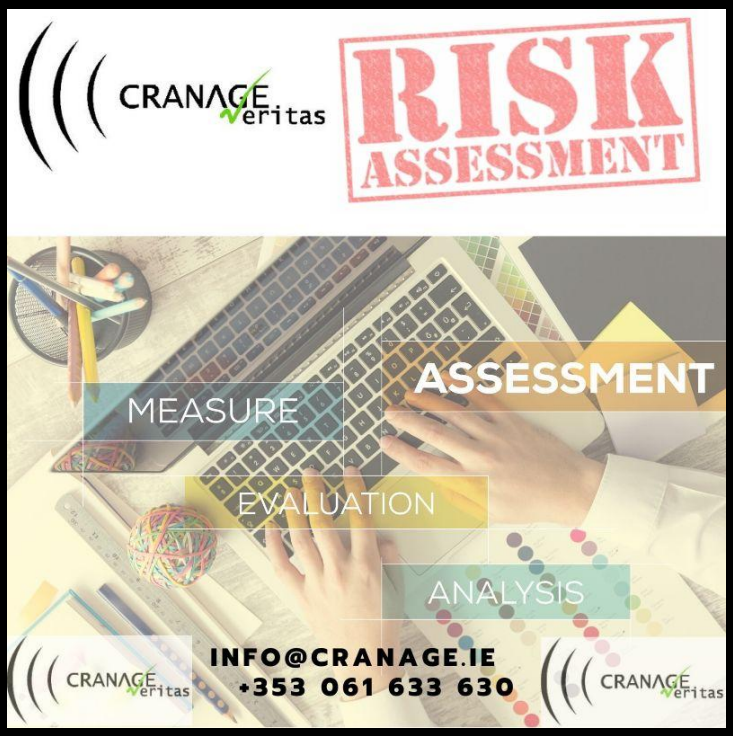
PRODUCT RISK ASSESSMENTS



Risk assessments are often a mandatory part of the product conformity process, and it's essential to ensure your product's risk assessment covers the scope of the device.
More and more standards require a risk assessment as part of the evidence for conformity.

Why use Cranage Veritas for a product risk assessment?

Our expert multi-disciplined engineers have the breadth of knowledge to assess the risks of all aspects of a product and its use. The benefit of this is that it can help to identify hazards that can then be mitigated out of the design before final conformity testing. This could save development time and prevent a product failure at the final testing stage – saving you time and money.

Who sees a product risk assessment?

The design engineers and quality production team view the risk assessment and use the identified hazard considerations to design out any risks before the final product conformity testing. The risk assessment will also be evaluated by the Notified Body if a Notified Body assessment is required for the product.

Does a product need a risk assessment?

It's always worth assessing the risks associated with a product, and a product risk assessment helps by considering all potential vulnerabilities. Our expert engineers consider all aspects of the product and its components to offer a comprehensive insight into the potential hazards. This allows a designer the opportunity to redesign and alleviate the risk. A risk assessment is useful for identifying design modifications as our engineers can then reassess the product to consider if the risk likelihood has reduced and if the design is at a safe level.

By completing a risk assessment throughout the design process the hazard is fully considered in terms of its:

- Occurrence
- Risk
- Severity
- Likelihood

Whilst domestic products don't have to have a risk assessment, a manufacturer does have to identify a hazard in order to avoid product failure. A risk assessment should be done to allay risk and could be an important consideration particularly when working with evolving technology and with no formal standards linked specifically for the product being developed.

Risk Assessments and the Medical Directive:

Designing a medical device? Then it's essential to note that all medical devices must have a risk assessment.
ISO 14971 is a standard used for the application of risk management for medical devices; it relates to all aspects of the medical device, and in some cases any other connected devices. Depending on the medical device, the risk assessment can be very large covering, as an example: biocompatibility, software , system security, electrical hazards, moving parts, patient and operator misuse, usability, EMC and environmental issues, to name a few.
The medical device must have an FMEA - Failure, Mode and Effects Analysis - carried out, where each component and its longevity is also considered.

A risk assessment is an essential part of the Medical Directive and the referred standard ISO 14971 outlines the mandatory requirements needed in the risk assessment - our engineers are experts in this area and can assist in preparing your medical device risk assessment.

How to find out more:

The expert team of engineers at Cranage Veritas have extensive experience reviewing clients' risk assessment files to ensure they meet the requirements of the regulations and standards. Contact us for more information, or for a bespoke risk assessment quote:

jon.jones@cranage.ie

☎ +353 061 633 630