

## **Newmac's proposal for reviewing existing CE supporting technical documentation.**

**Aim:** To audit the supporting documentation for the units CE compliance. This is a "health check" to ensure that you are meeting your legal obligations in supplying equipment into the European market.

Our compliance assessment covers legislative requirements, and also consideration of the equipment in use to ensure that it is fit for purpose and safe across its lifecycle.

### **Our review encompasses the following areas:**

- The equipment has the correct CE supporting declarations.
- The CE declarations display correct information and are issued to the relevant personnel.
- The technical files contain relevant risk assessment data to cover the design life of the machine. That these are completed by trained and experienced personnel.
- 3<sup>rd</sup> party component information is held, and where necessary meets the level of safety and reliability recommended by standards.
- Safety systems are clearly identified within the design, and good engineering practice including redundancy, and back-up are applied. These component configurations need to demonstrate the critical limits for potential unit failure.
- Supporting documentation such as manuals for use, maintenance and repairs meet the required standard.
- An approach by regulatory authorities in the event of an incident can be dealt with professionally.
- That the technical files are updated with design changes, encompassing new technology and data from relevant industry sector reports.

### **How Newmac provide this service.**

- We issue a pre-audit document to fully establish the scope of the company's equipment range and markets supplied.
- A site visit will be scheduled in, where we will carry out an independent assessment of the documentation. Where appropriate we will also accompany your authorised personnel with field testing.
- Provide a summary report, identifying actions in the following areas;
  - i) Missing or incomplete documentation.
  - ii) Updates to standards and legislation.
  - iii) Challenge the robustness of document systems in the event of a product recall and investigation.
  - iv) Explain how Newmac can support your team in developing your product safety knowledge, ensuring compliance brings added value to your business.

Please note that we respect the competitive nature of the industry and are willing to comply with non-disclosure agreements to ensure client confidentiality.

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