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CE Mark "Step by Step" Procedure

TECHNICAL FILE

Your first step is to call us at 847-537-6400.

We will help you:

1. Determine, which directives and standards will be applicable for your product
2. (See other "Step by Steps" for your product)
3. Confirm which harmonized standards can be used for the presumption of conformity to applicable Directives.
4. Test at D.L.S., an accredited testing organization

You will receive from D.L.S.:

Formal test reports to cover all testing.

You will then need to:

1. Issue the manufacturers Declaration of Conformity, after you have met all the essential requirements of "all" applicable Directives.
2. Place the CE mark on your product.
3. Assemble a Technical File for your product. The Technical File is your documentation of how you met the CE marking requirements for your product. The file should not be confused with a Technical Construction File which is used by a manufacturer to show compliance via a non-harmonized route. This Technical File contains as a minimum the following:
 - A. Adequate analysis and assessment of the risk(s)and
 - B. A copy of your Declaration of Conformity (DoC) or the original if you do not have a representative in Europe.
 - C. A table of contents.
 - D. A description of your product and how it works.
 - E. Bill of Materials showing sub components and accessories
 - F. Instructions on how to operate your equipment.
 - G. A complete set of schematics for the product and any relevant information to document how it was designed and built to comply.
 - H. results of design calculations made, examinations carried out, etc

You will then need to (continued):

3. Assemble a Technical File (continued):

- I. A list of the harmonized standards and/or other relevant technical specifications, the references of which have been published in the Official Journal of the European Union, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the legislative instrument where those harmonized standards have not been applied. In the event of partly applied harmonized standards, the technical documentation shall specify the parts which have been applied.
- J. A copy of the reports and documentation of how you fulfilled each directive requirements for CE Mark

Examples of CE Marking Directives are:

Electromagnetic Compatibility Directive (EMC) 2014/30/EU

Radio Equipment Directive (RED) 2014/53/EU

Low Voltage Directive (LVD) 2014/35/EU

Medical Device Directive (MDD) 93/42/EC

Machinery Directive (MD) 2006/42/EC

Reduction of Hazardous Substances (RoHS) 2017/65/EU

5. Market your product in all of Europe.

Please understand that the EU EMC requirements for your product and the interpretations of the requirements may change. Please check with D.L.S for latest updates. These potential changes create risk, but we believe that your greatest risk would be to do nothing.

Call **D.L.S. Electronic Systems, Inc.** at **1-847-537-6400** for any questions you have about EU testing, scheduling and cost. We will be most happy to assist you. Visit our Website at **www.dlsemc.com** or Email us at { **HYPERLINK** "**mailto:jblack@dlsemc.com**" }