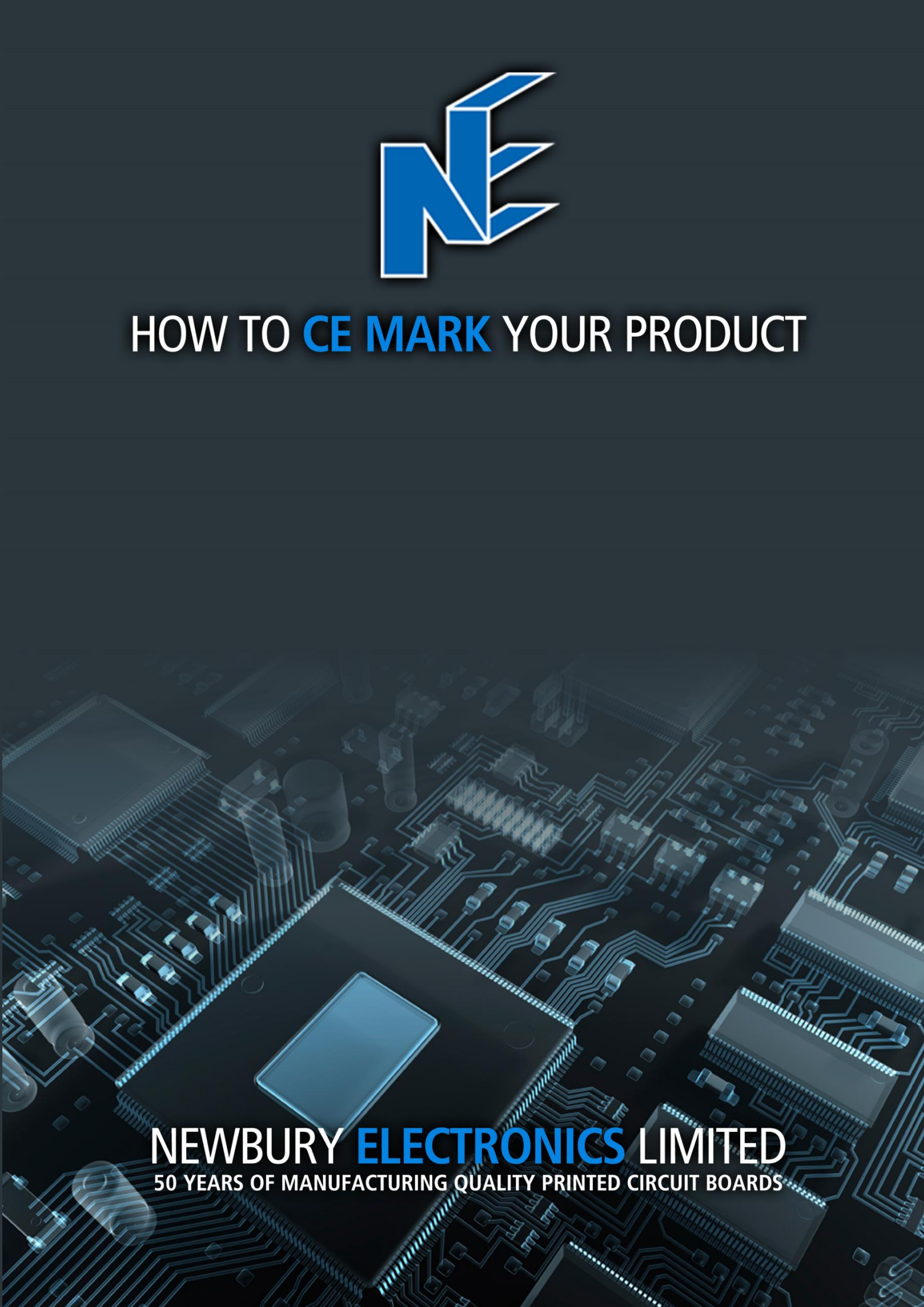
HOW TO CE MARK YOUR PRODUCT



NEWBURY ELECTRONICS LIMITED

50 YEARS OF MANUFACTURING QUALITY PRINTED CIRCUIT BOARDS

Introduction

"CE marking your new product is not as difficult or as expensive as you probably think."

CE marking your new product is not as difficult or as expensive as you probably think. Many entrepreneurs worry that the process will drain them of cash, bury them in regulation and paperwork and leave them exposed if they do not do it exactly right.

If you are clever about it, it is none of these.

The first thing to understand is that there is no such thing as a perfectly certified CE product. The amount of time you invest in it is up to you but the responsibility for making sure you have invested enough is also up to you. It is a self-certification process.

The only part of CE marking an electronic product that really means you have to reach for your cheque book is EMC (electromagnetic compatibility/interference) testing - and sometimes not even that if your environment is not too onerous or sensitive.

It will be necessary to make sure the administration is strictly controlled. It must be issue controlled and properly backed up. An enormous amount of money can also be saved by designing for EMC properly and going to the EMC test house properly prepared.

Look out for an article on EMC design and test, coming soon.

The caveat I would add here is that there is a lot of administration to do. The best kind of person to do it is one that has a good working knowledge of your product and that has the time to spend on a considerable amount of administration.

If you have the resources you can buy software to help you with this – but you don't have to and it is probably only worth it if you have budget to spare.

If you need any further help or advice with the process, please do not hesitate to get in touch with us at info@newburyelectronics.co.uk.

The CE Marking Process

You need to build what is called a 'technical file'. The best way to do this is using a computer and word processor - you can think of it like a lever arch file.

This is how companies have done it for years and if you were to audit a few I am sure they would still have lever arch files. The technical file is built into the following sections:

1. **Description and Intended Use**
2. **Design Specification**
3. **Verification and Validation**
4. **Essential Requirements**
5. **Instructions for Use**
6. **Labelling**
7. **Manufacturer Details**
8. **Manufacturing Specification**
9. **Product Classification**
10. **Risk Analysis**
11. **Standards and Specifications**
12. **Declaration of Conformity**

Note: *You do not have to repeat information already held in these sections. For example, you only need make reference to user instructions - they do not actually need to be in the technical file.*

1. Description and Intended Use

This is a Statement of Description and Intended Uses which will occupy about one side of A4 paper. It will outline a description of the product and the potential applications that it is intended to be applied to.

It is important not to 'overstate' the intended uses because it can result in a need to comply with unnecessary standards.

2. Design Specification

The Design Specification will cover all the important technical details which define the performance of the product. The following is a non-exhaustive list: temperature requirements, electrical, mechanical, chemical and environmental.

3. Verification and Validation

Design Verification and Validation Certification (i.e. testing) will be required to cover the 'fitness for purpose' of the product. This will include testing to meet national or international standards that have been deemed applicable.

This can include testing done by external test houses, trials, testing within the company or any other sort of testing which verifies that the product conforms to the Design Specification.

EMC testing (and sometimes safety testing) under EN60601 form the most expensive parts of this but there are routes to minimise their impact.

4. Essential Requirements

This is rather laborious. It is a clause by clause check of the applicable European directives confirming that each is met. Some companies also validate against international and national standards using the same technique.

It is usually done in tabular form. The directives that apply are chosen by the company wishing to place the product on the market. A list of all the directives and a download site can be found here.

This site also gives some standard tables for essential requirements verification. This can save you time as you simply can look at all the directives shown on this site and decide which apply to you. You can usually do this from the title. For example, if you are manufacturing an electronic product used in industry you do not need to worry about the toy directive!

Sometimes it is more complicated than this. For example, if you make an electronic product that uses a 20V dc supply, do you need to meet the 'low voltage directive'? (Answer: no). This requires some reading of the directive itself.

Do not be put off by the legalistic format of the directives – they do contain the information you require and you just need to read them.

5. Instructions for Use

You probably already have these. If your product requires instructions on how to use it they should be identified here. Also note that you should put the CE mark on them.

6. Labelling

Labels used on a device form an essential part of the CE requirements. It is suggested that a montage of all labels proposed for use both internally and externally on the product should be created with a legend showing where they have to be placed on a production unit.

These will need to be checked for CE conformity against the current standards that are applicable. It is required, if the product is big enough, that the contact details are prominently displayed on the product and/or packaging.

7. Manufacturer Details

The manufacturer details of all sub-components of the unit will have to be collated (generic details - not piece by piece component details). It will be necessary to state the credentials of these suppliers and preferably approvals they hold.

Think of this as your supplier review section. In short, you just need to make a list of all the suppliers you use, state their credentials (ISO9000 or not, capabilities and more if you have the data from performance reviews).

The most professional contents for this section would show (or better refer to) full vendor appraisal but do not worry if you do not have this.

"Labels used on a device form an essential part of the CE requirements."

"Risk analysis doesn't have to be enormously complicated."

8. Manufacturing Specification

This is a complete description (or references to where data is held) of the processes and material necessary to produce the product.

It holds the data needed to produce the product and, if completed correctly, it would allow any competent resource to manufacture the product. It will hold things like bills of materials (BOM) and technical drawings.

9. Product Classification

European directives sometimes classify products that they describe. It may be necessary to follow this classification and it will then lead to steps that will need to be taken to result in compliance.

This section is a rare exception. Most products on the market place don't require this. Examples of those that do are those that fit into the Medical Device Directive or the Pressure Directive.

Both of these require you to classify your product which is quite understandable (a special pair of scissors for removing hair before an operation would require much less scrutiny than a ventilator that breathes for you when you are under anaesthetic).

10. Risk Analysis

Risk analysis doesn't have to be enormously complicated. It all depends on the impact failure of your product could have. The most thorough way to cover this is to do failure mode and effect analysis (FMEA) and manage it in accordance with an international standard (there are rather a lot of these).

However, for a not too ambitious product with low risk you can do a simple risk analysis.

11. Standards and Specifications

This section will identify all relevant standards to which the product is required to meet. This section overlaps with others above. It is effectively a list of the applicable standards.

So, if you are making a floating toy for children to use in a swimming pool you need to find out if there are any national or international standards (BS EN) that apply to it. These should all be identified in this section.

12. Declaration of Conformity

This will ultimately have to be signed by senior management of the company wishing to place the device on the market. This will state that all due diligence and proper procedures have been undertaken, all national and European Standards have been met, and the product fully conforms to all requirements for CE approval.

This document is the written declaration of conformance with EU directives and it is this document that you will use if you wish to prove to others that you have been through the process.

Simply populate these sections and you have done it.

Go ahead and put the CE mark on your product and call it CE marked.

The Benefits of CE Marking

I think it could reasonably be asked 'Why do all this? What has it done for my business?' The answers are fairly straight forward:

- You will find it difficult to get ISO9000 approval without it – or something as thorough.
- You now have a robust design file that means your product is professionally supported.
- If one of your customers asks for you to show your CE credentials you need only send him your 'Declaration of Conformity'.
- There is evidence that you have demonstrated 'due diligence' in the development of your product. It will be to your benefit in any dispute.

About Newbury Electronics

Newbury Electronics offers full printed circuit board (PCB) services, from design to manufacture, assembly and testing. The company's origins began in 1956 and every year we produce over 10,000 PCB designs for our clients.

For more information about Newbury electronics and the services we offer please visit www.newburyelectronics.co.uk.

Questions and Comments

After downloading this white paper you will be directed to a page where you can leave feedback and ask questions regarding the CE marking process.

You can find the blog post here.