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The OEM Manufacturer Dilemma.

According to the famous European **R&TTE Directive** (ANNEX II items 2 and 3)

1. The manufacturer must establish the technical documentation (….) and he or his authorised representative established within the Community must keep it for a period ending at least 10 years after the last product has been manufactured at the disposal of the relevant national authorities of any Member State for inspection purposes.
2. Where neither the manufacturer nor his authorised representative is established within the Community, the obligation to keep the technical documentation available is the responsibility of the person who places the product on the Community market.
3. The manufacturer or his authorised representative must keep a copy of the declaration of conformity with the technical documentation.

In addition the **R&TTE Directive** states (Article 6.3):

1. Member States shall ensure that the manufacturer or the person responsible for placing the apparatus on the market provides information for the user on the intended use of the apparatus, together with the declaration of conformity to the essential requirements.

Furthermore the "**Guide to the implementation of directives based on the New Approach and the Global Approach**", Chapter 5.4 "EC declaration of conformity" states that the following information should be provided in the declaration of conformity (DoC):

1. the name and address of the manufacturer or the authorized representative issuing the declaration; the identification of the product (name, type or model number, and any relevant supplementary information, such as lot, batch or serial number, sources and numbers of items);

2. (….) the name and address of the person who keeps the technical documentation.

With this in mind let's have a look at what this means to an OEM manufacturer wishing to place products on the European market.

It is the OEM manufacturer's business to sell his product to multiple customers. These customers will possibly re-brand the equipment and to place it on the market.

OEM manufacturers will find their customers in various ranges of the market. They can be sales companies using the OEM device as addition to their sales catalogue. But they can also be large corporations who will use the OEM product as added value to their own product-line. Even a competitor looking for a fast way to the market can decide to buy a product from an OEM company.

As most OEM manufacturers are not established within the European Union and will do not have an authorised representative within the EU either, responsibility for following the European rules are placed with the person responsible for placing the apparatus on the market.

This means that the procedure of making sure that the equipment is sold legally has to be repeated every time a customer decides to place the product on the European market.
Part of the procedure is that a Technical File or a Technical Construction File has to be created. The data for these files will have to be provided by the OEM manufacturer.

This situation is not ideal for the OEM manufacturer for the following reasons:

- The need to repeat the procedure will cost a lot of time and money.
- The OEM manufacturer will have to make strategic design- and manufacturing information available to companies who may be their competitor.
- The OEM manufacturer has no control over the procedure. If a customer says that everything necessary has been done, the manufacturer can only believe it.
- The technical file must be kept and maintained until 10 years after the final production date. I will prove very difficult to manage the multiple technical files at various locations.

Is there a solution to this problem? Sure there is!

CE-Real is available to manufacturers to act as their authorized representative within the European Union.
Having **CE-Real** as your representative will take away the above mentioned reservations:

- Only one single technical file will have to be created and filed. Various OEM models to be shipped to the EU market can be added as Appendix to the original file.
- The strategic design- and manufacturing information will be kept in a safe place (actually at least two places to avoid loss due to fire or other accidents) and the contents will be secure following the signing of non-disclosure agreements
- CE-Marking is our business, so you can be sure everything will be done according to the EU rules and regulations
- There will be one single version of the technical information on file. Therefore maintenance will be simple. Further it will be easy to guarantee that the file will be kept as long as it is required. Even possible reorganizations or personnel changes in the manufacturers organization will not have the risk that the file gets 'lost' over time.

We hope that we have been able to give you some insight in the workings of the procedures in the European union.

Should you wish to discuss this white paper with us or if you want to investigate the possibilities to have CE-Real help you onto the European market, please feel free to contact us. Relevant contact information can be found in the header of the first page of this document.

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