



# languageintelligence

Professional Language Services

## White Paper

*Translation, the European Union and the IVD Directive*  
Life Sciences / Medical Device Industry

In 1994, the countries of the EU/EC and the EFTA joined to create the largest economic region worldwide, the European Economic Area (EEA). Today, participating members include Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxemburg, the Netherlands, Norway, Portugal, Spain, Sweden and the United Kingdom. This region is also commonly referred to as the EU (European Union).

## Enlargement

Expanding the EEA is vital for its continued development. Admitting additional member states, or “Enlargement”, is a continuous process and it can be expected that other countries will apply for membership in the EU. In 1993, the European Council determined the criteria for membership. The timing of candidate countries’ accession to the EU depends on the progress they make towards the following criteria in preparing for membership:

stable institutions guaranteeing democracy, the rule of law, human rights and respect for and protection of minorities;

a functioning market economy with the ability to cope with competitive pressure and market forces within the EEA;

the ability to fulfill the obligations of membership, and the adherence to the goals of political, economic and monetary union.

Enlargement will present significant economic opportunities in the form of a larger market. Negotiations for membership are under way with 12 applicant countries. On 9th October 2002, the Commission established that the negotiations on accession to the European Union should be concluded by the end of

2002 with the following 10 of the candidate countries: Cyprus, the Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, the Slovak Republic and Slovenia. Negotiations with Turkey have not yet begun, as it does not yet meet the political conditions for membership. The Commission recommended that the EU strengthen its support for Turkey’s pre-accession preparations and that additional resources be provided for this purpose.

## Large market = New opportunities

According to the Commission, those candidate countries with whom negotiations have been concluded will be ready for membership at the beginning of 2004. Regarding Bulgaria and Romania, the Commission determined that the year 2007 chosen by these two countries be regarded as a target date for accession, provided that they meet the accession criteria and conclude the negotiations. The addition of these countries to the over 370 million inhabitants of the EU’s Single Market would create the biggest economic area in the world. This enormous market increase will provide immediate opportunities for economic development, and raise levels of prosperity throughout all member states of the EEA.

In order to protect the health of consumers and workers, as well as the conditions of the merchandise and the environment, the European Council created EC Directives to ensure conformity to supranational safety and quality standards throughout the EU and some members of the European Free Trade Association. Most of the legislation and procedures are now in place and the goal of “harmonization” for existing directives and guidelines is, for all practical purposes complete. In order to support the directives’ essential requirements, the standards for product safety, machinery and electromagnetic compatibility (EMC) have been published. This standardization is an evolutionary process, with established procedures to

## Harmonized Standards and the EC Directives

Product compliance is based on an understanding of the goals of compliance, which are explained in the laws known as directives. The technical rules for realizing these goals are explained in the harmonized standards known as ENs.

Together, the directives and standards form the basis for a product's design and assessment criteria. The governing principle is the protection of the consumer (end-user, operator, buyer, etc.). This framework also serves to minimize the potential liability risks to the product manufacturer and supplier.

## Presumption of Conformity

European national authorities are required to recognize that any product or device manufactured in compliance with the European harmonized standards is presumed to conform to the essential requirements of the directives. The standards are published in the Official Journal of European Communities. Conversely, the presumption of conformity does not exist for products or devices not in compliance with the relevant ENs.

There are three primary areas in which ENs are concerned:

- The Quality and Competence of the Bodies responsible for
  - Accreditation
  - Testing
  - Certification
  - Surveillance (i.e.: EN45000)
- The Quality and Competence of Manufacturers (i.e.: ISO 9000)
- The Quality, Safety and Reliability of Products

## EC Directives

There are three types of product-related directives:

### Basic Directives

These apply to all manufacturers of products and deal with trade, enforcement, liability and other issues. Examples of the basic directives are CE Marking, Conformity Assessment, General Product Safety and Product Liability. Examples of the Basic Directives that apply to most products and suppliers are:

- General Product Safety Directive - 92/59/EEC
- Product Liability Directive - 85/374/EEC
- Conformity Assessment Procedures and CE Marking Rules - 93/465/EEC
- CE Marking Amendment - 93/68/EEC

### Generic Directives

These deal with a specific product group, such as products that may generate Electro-magnetic emissions (EMC). These directives were designed to address the "unregulated" sector of products. Instances of unregulated products are IT equipment (ITE), household appliances, etc.

### Product-Specific Directives

These apply to "regulated" products, such as telecom and medical, and other products where extreme hazards exist. For classes or types of products that are regulated by a directive, assessment and certification by a EU Notified Body is required before the CE Marking can be obtained. Product-specific

## The Directive 98/79/EC-In vitro diagnostic medical devices (IVDD)

### What is in vitro testing?

The results of in vitro tests are a unique source of objective information about a person's state of health or disease. Valuable information can be obtained by taking samples (for example blood, tissues or urine) from the body and performing tests on these samples. Tests include measuring the concentrations of various chemical and biochemical components, counting cells, measuring physical properties of the sample, microscopic examination of cells and other structures or making biological cultures. Health care professionals refer to these tests as in vitro diagnostic (or IVD) tests because many were originally performed in a test tube (in vitro is Latin and means literally "in glass") and because they are mostly used to help determine or diagnose what is wrong with a patient.

While many medical laboratory tests are used in diagnosis, perhaps in connection with an infection or an accident, in vitro tests are increasingly being used to monitor the treatment that is given. One of the first steps after a medical examination is often to take a blood sample and to request the medical laboratory to carry out a number of in vitro tests. The results of the tests are used in disease management to assist the doctor (in the hospital or in general practice) in making the best decisions about treatment.

### What are "in vitro diagnostic medical devices" as defined by the IVDD?

The Directive applies to in vitro diagnostic medical devices and their accessories. For the purposes of the Directive, accessories shall be treated as in vitro diagnostic medical devices in their own right. The following definitions shall apply:

#### **'in vitro diagnostic medical device'**

This means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment, or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information:

- concerning a physiological or pathological state, or
- concerning a congenital abnormality, or
- to determine the safety and compatibility with potential recipients, or
- to monitor therapeutic measures.

Specimen receptacles are considered to be in vitro diagnostic medical devices. 'Specimen receptacles' are those devices, whether vacuum-type or not, specifically intended by their manufacturers for the primary containment and preservation of specimens derived from the human body for the purpose of in vitro diagnostic examination.

Products for general laboratory use are not in vitro diagnostic medical devices unless such products, in view of their characteristics, are specifically intended by their manufacturer to be used for in vitro diagnostic examination.

### What kinds of products do manufacturers of in vitro diagnostics tests make?

The IVD industry produces analytical instruments and the reagents that are used to perform certain tests. Reagents are solutions of highly specific biological or chemical substances that are able to react with target substances in the samples to produce a result that can be measured or seen. The analytical instruments are the various machines and equipment that automate the process and are used to bring samples and reagents together and to measure the result, or to measure other qualities or parameters in the samples.

Accessory products such as the software programs used to run the instrumentation and control solutions to check the performance of the systems, are also produced by the IVD industry. Together the reagents, the instruments, and the accessories are referred to as in vitro diagnostic “systems”.

## EC Directives - Technical File

A technical file is required by the primary directives to document the conformity assessment and the product's design. The technical file shall be compiled by the manufacturer or authorized representative and contain design and manufacturing documentation, test reports and operation information to show conformity as required by the directives.

## CE Marking: The CE Mark

The letters “CE” represent the acronym of the French phrase “Conformité Européene” which translates into “European Conformity”. The initial term used was “EC Mark”. It was officially replaced by “CE Marking” in the Directive 93/68/EEC in 1993. All official EU documents today use “CE Marking”. Although “CE Mark” is also used, it is not the official term.

According to the new rules, in vitro diagnostic medical devices must carry the CE Marking as a visible sign that the manufacturer has complied with the new procedures and that the products fulfill all applicable requirements. CE Marking and a Declaration of Conformity are mandatory for most products sold in the EU. While the CE Marking does permit a product to be placed on the EU market, it is not an implicit or explicit approval mark, certification or quality mark. CE is a “Marking” that is simply a declaration that the manufacturer or supplier has taken responsibility for conforming to the essential requirements of a directive.

Except for some high-risk products, most products can be self-assessed by the manufacturer as to whether they meet the Essential Requirements. To achieve compliance with the Medical Device or the IVD Directives, however, manufacturers may need to work with an independent, third-party company – a Notified

Body – as a key part of the CE Marking process. It is the Notified Body's responsibility to certify that the manufacturer and its products are in compliance with directive requirements.

## The CE Marking is:

- indicates a product's conformity with the “essential requirements” of the directives
- permits products' access to the market
- ensures the “free movement of goods”
- allows the “withdrawal of non-conforming products” by customs and enforcement authorities

## The CE Marking is not:

- a mark or certification or approval issued by a third party
- simply a marketing or promotional tool
- a quality mark
- for components\*

\*(Although there are some exceptions, the vast majority of components do not need CE Marking.)

## Affixing the CE Marking

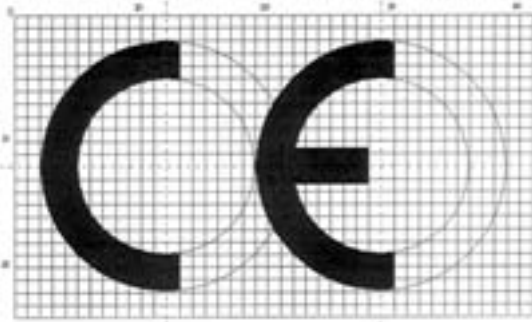
The manufacturer is responsible for ensuring that their products meet the essential requirements of the applicable directives before affixing the CE Marking to the products. The CE Marking must be shown on the device or, if not possible, on its packaging. The CE Marking will not prevent national enforcement bodies from taking action against products or manufacturers if marked products are determined to be non-compliant (see “Non-compliance Risks”).

## The 5 Steps to European Conformity

- Identify all applicable Directives and Standards
- Assess product according to the “Essential Requirements” and “Harmonized Standards”
- Complete the “Technical File”
- Prepare and sign the “Declaration of Conformity”
- Affix the “CE Marking”

## CE Marking Guidelines

The CE conformity Marking shall consist of the initials “CE” in the following form:



- If the CE Marking is reduced or enlarged, the proportions given must be respected.
- The various components of the CE Marking must have substantially the same vertical dimension, which may not be less than 5 mm.

## Non-compliance Risks

In case a Member State authority establishes that a CE Marking has been affixed unduly, the manufacturer/agent shall be obliged to make the product comply to the provisions concerning the CE Marking and to end the infringement under conditions imposed by the Member State. If non-compliance continues, Member States must take all appropriate measures to restrict or prohibit the placing of the product in question on the market or to ensure its withdrawal from the market.

## Translation and the In Vitro Diagnostics Directive

How do the IVDD (In Vitro Diagnostic Directive) and the MDD (Medical Device Directive) differ?

The IVDD applies specifically to in vitro products, i.e., medical tests or devices that examine human fluids or tissue samples to identify, diagnose, and manage medical conditions. Like the Medical Device Directive (MDD), the purpose of the IVDD is to ensure supranational legislation rather than costly national legislation.

The IVDD is the third in the family of medical device directives (along with the MDD, Medical Device Directive and the AIMD, Active Implantable Medical Directive).

What are the relevant deadlines for complying with the In Vitro Diagnostics Directive (IVDD)?

The IVDD was published as Directive 98/79/EC on December 7, 1998. The European Member States were given 12 months to transpose the IVDD into national law. For more detailed information please refer to section “The Directive 98/79/EC-In vitro diagnostic medical devices (IVDD)” in this document.

According to the new rules in vitro diagnostic medical devices must carry the CE Marking as a visible sign that the manufacturer has complied with the new procedures and that the products fulfill the essential requirements that apply to them. As of June 7, 2000 it is possible to obtain CE Marking for in vitro diagnostics.

After December 7, 2003 only CE-marked devices may be placed on the European market. This will affect all new products subject to the directive introduced in the market place. Two years later, after December 7, 2005, only CE-marked devices can be put into service.

## Which countries and languages are affected by the IVDD?

All countries and languages of the European Economic Area are affected (currently 12 languages). Article 4.4 of the IVDD allows Member States to require information supplied with an IVD device to be in local languages when the product reaches the end-user. The current language requirements as interpreted by “Medical Device Safety Service” can be reviewed here. Please be sure to read their disclaimer. You may also review [mdieuropa](#) for information on language requirements in the EEA (European Economic Area). Since all Directives are binding for all EU member states, it is safe to assume that any new EU members will establish similar language requirements.

The EEA is an evolutionary group with explicit provisions for enlargement. In recognition of the market potential and regulatory benefits that come with EU membership, many countries have been applying for accession to what promises to be one of the largest unified markets in the world. Currently, negotiations for membership are under way with 13 applicant countries (not yet with Turkey, which does not yet meet the political conditions). On October 9th 2002, the Commission recommended to close negotiations with Cyprus, the Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, the Slovak Republic and Slovenia. The objective is that the first group of new members should join the EU in time for the elections to the European Parliament scheduled for June 2004. For more information please check the Report of the European Commission.

## How can we minimize the cost for translating into all of these languages?

In vitro diagnostic manufacturers and the industry are concerned about the costs associated with complying with the new requirements. Their concerns focus on increased end-user costs for in vitro diagnostic devices, disadvantages for the public health sector for certain smaller countries as products may no longer be available, and a potentially negative impact on product safety resulting from decreased label legibility because of smaller font sizes for multiple languages. While some countries may grant possible exclusions from the language requirements, these exclusions are currently ill-defined. In addition, the manufacturer will likely need to apply for exclusions on a per-product basis in every country that may grant such exclusions. The potential cost for documenting reasons for exclusion, as well the regulatory steps to be taken, may well outweigh the cost of complying with the directive.

You can effectively control your company's translation expenses by working closely with your translation vendor and others involved in the localization process. Language Intelligence has several years of IVDD experience and has developed a controlled process to assist manufacturers with IVDD compliance.

## Appendix A - Additional Directives

Directive:	Date for Mandatory CE Marking
Active implantable medical devices (90/385/EEC)	1/1995
ATEX equipment (94/9/EEC)	6/2003
Boilers (92/42/EEC)	1/1988
Construction products (89/106/EC)	4/1998
Electromagnetic Compatibility EMC (89/336/EEC)	1/1996
Explosives (93/15/EEC)	1/2003
Gas appliances (90/396/EEC)	1/1996
General pressure equipment (97/23/EC)	5/2002
Low-voltage electrical safety (73/23/EEC)*	1/1997
Machines (98/37/EC)	1/1995
Medical devices (93/42/EEC)	6/1998
Non-automatic weighing machines (90/384/EEC)	1/1993
Passenger lifts (95/16/EEC)	7/1999
Personal protective equipment (89/686/EEC)	7/1995
Recreation craft (94/25/EEC)	6/1998
Simple pressure vessels (87/404/EEC)	7/1992
Telecommunications terminal equipment (91/263/EEC)	11/1992
Toys (88/378/EEC)	1/1990
*(for products operating at 50-1,000 VAC or 75-1,500 VDC)	

## Appendix B - Definitions

### In Vitro

An In Vitro biological study is one which is carried out in isolation from a living organism (in contrast to In Vivo studies).

### reagent

A reagent is a chemical substance that is used to create a reaction in combination with some other substance. For example, Small Particle Reagent (SPR), a suspension of molybdenedisulfide powder in a detergent solution, is used for fingerprint detection on wet, oily, or dirty surfaces which may be unsuitable for other methods. The powder particles cling to the lipids in a fingerprint, thus rendering the fingerprint visible. Grey prints appear that can then be lifted from the surface with tape.

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## About Language Intelligence

Language Intelligence breaks down language and culture barriers to help you succeed in global markets.

Our language translation services prepare your documentation and our culture and language training programs prepare your staff. Language Intelligence combines experienced project managers, highly skilled technical staff and professional linguists and cross-cultural experts with an ISO 9001-2000 compliant quality management system to make your company a success in a variety of diverse global markets.

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