



E-Labeling Services

for in vitro diagnostics

Provide instructions for use over the internet in full compliance with European regulations !

Does this sound familiar?

- Annual printing cost for instructions for use higher than 100000 €/year
- Thick multilingual instructions for use do not fit in the kit box
- Instructions for use almost illegible due to small font
- Obsolete inventory after revision of instructions
- Shipping more than 2 tons (!) of instructions for use per year

...Qarad E-Labeling Services provide a solution

No more paper leaflets!

Your customer in the laboratory downloads the instructions for use from www.e-labeling.eu or asks a paper copy by calling our European-wide freephone service.

Qarad E-Labeling Services include two components

A dedicated website

- specifically designed to manage your instructions for use
- and to make it available to your customers without risk for error.

A European-wide multilingual freephone service

- Free telephone numbers accessible from all European countries
- Telephone operators answering phone in your customers' language

Regulatory context

Qarad E-Labeling Services are fully compliant with MEDDEV 2.14/3 rev.1.

This official guidance document describes the conditions in which manufacturers of IVD products can make instructions for use available to the user. These include:

- instructions for use must be on a dedicated website or a dedicated area of a website
- data security requirements
- users must have the opportunity to ask a copy of the instructions for use by calling a free telephone number !
- the system must be based on risk management principles.
- Point-of-care tests and IVDs for self-testing are excluded



E-Labeling Services

Our support

- In compliance with European regulatory requirements.
- Validation of the website and the freephone services.
- Validation packages available.
- Designed after risk analysis.
- Advise on labeling.
- Assistance in implementation.

... Qarad E-Labeling Services provide a complete solution.

The website

User friendly

For both yourself and your customer, the website is very user friendly and designed to prevent errors in downloading the right instructions. The website is multilingual. Your customer can go through the downloading process in his own language. It is entirely web based: no software to be installed.

A powerful marketing tool

The user, who needs instructions for use, will land on a page that you can design in agreement with your house style. Your customers will frequently visit the website to download instructions for use and this will give you direct exposure to the end users of the products. You can easily modify the web pages and use it to communicate directly with the users of your products. The web page contains your contact information, a link to your company's website and news items, such as announcements of new products, which you can easily upload on the pages.

Safe

Much attention is paid to security and data protection. Extensive validation ensures correct performance.

The freephone service

Qarad E-Labeling Services include free telephone numbers accessible from *every country* in the EEA and Switzerland. Our operators answer your customer in his own language and we forward him the instructions without your intervention. Our service protects you from abuse of the free telephone numbers for other purposes (complaints, orders, ...).

Qarad
Volmolenheide 13
B-2400 Mol
Belgium
Tel.: +32 14 32 38 99
Fax : +32 14 32 63 84
qarad@qarad.com
www.qarad.com