European Diagnostic Manufacturers Association

EDMA position paper

LANGUAGE REQUIREMENTS FOR TEXTS DISPLAYED ON SCREENS IN INSTRUMENTS FOR PROFESSIONAL USE

Update

28th August 2009

Rationale

The purpose of this EDMA Position Paper is to define whether or not the text displayed on screen must be considered as Instructions for Use. Consequently, whether or not, translation is required in the case of IVD Instruments for professional use.

For IVD Instruments for self-testing, taking into account the type of users, the need to provide full translation of the whole instrument documentation, including the texts displayed on the screens, into the required national language(s), is clearly recognized by all parties.

Introduction

Legal requirements regarding the language in which information is to be supplied by the manufacturer are set down are in Article 4.4 of the IVD Directive (IVDD).

The requirements for the contents of this information are set down in Annex I.B of the IVDD, in sections 8.1-8.7 (Information provided by the manufacturer).

Labelling

Labelling is understood to mean the information provided for the proper and safe use of the device, i.e. Labels and Instructions for Use (IFU).

Labels:

Whenever possible, the labels should be attached to the In Vitro Diagnostic medical device itself (texts and symbols are equally acceptable). More details are outlined in Annex I.B paragraphs 8.1 (3) and 8.4 of the IVDD.

Instructions for Use

IFU must comply with Annex I.B, paragraph 8.7 of the IVDD. However, following the introduction of MEDDEV 2.14/3 these do not necessarily need to accompany each device or be included in the packaging of one or more devices , as specified in Annex I.B , paragraphs 8.1.4 and 8.1.5 of the IVDD.

The IFU can be provided separately by alternative means with the exception of devices specifically intended by the manufacturer for use at point of care. (For details refer to MEDDEV 2.14/3)

EDMA Position on Text Displayed on Screens

EDMA has now revised its original position in order to respond to trends in national legislations, which require IFU to be translated into national languages, and to align with accepted practices in the medical device area.

If an IVD system provides the instructions to the users by using a screen (monitor), these should be considered as IFU. Manufacturers should then assess the criticality of these instructions on the basis of risk analysis, considering factors such as the likely educational background and training of the users.

Therefore, where required as a result of the risk analysis, information and instructions that are considered as necessary for the safe and proper use of

the device should be translated into the required national languages.

Translated text can be provided:

- either on the screen itself, or
- in the IFU as translations of text displayed on the screen.

Providing the translated text using either method described above will allow the user to understand the instructions actually displayed on the screen itself and will thereby ensure the safe and proper use of the IVD medical device.

Conclusion

The IVD Industry believes that, any text displayed on the screens, when considered necessary for the safe and proper use of the device, must be considered as Instructions for Use and should then be provided in the appropriate languages.

Translations if necessary for the safe and proper use can be provided either on the screen itself or in the IFU as translations of the text displayed on the screen. Either method will ensure the safe and proper use of the IVD medical device.

Note: EDMA suggests that everybody checks in the countries of interest that no specific legislation contradicts this position.

References:

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVD Directive)

EDMA Guidance Document – Language Requirements for Professional Use in the EU, EFTA and Accession States.

The EDMA Labelling Task Force