LANGUAGE REQUIREMENTS FOR TEXTS DISPLAYED ON IVD SCREENS AND SOFTWARE

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The medical technology industry seeks to define whether the text displayed on the *in vitro* diagnostic medical devices (IVD) screens and software must be considered as instructions for use (IFU). Consequently, where, and how translation is required.

MedTech Europe argues that if an IVD system provides information following Annex I, Section 20.4 to the users by using a screen (monitor) or in software, these should be considered as instructions for use and should be translated into the appropriate languages.

Legal requirements regarding the language in which IVD information is to be supplied by the manufacturer are set down are in Article 10.10 of the IVD Regulation (EU) 2017/746 (IVDR). The requirements for the contents of this information are set down in IVDR Annex I, Section 20.

IVDs for professional use including IVDs intended for near patient testing

If an IVD system provides information following Annex I, Section 20.4 to the users by using a screen (monitor), these should be considered as instructions for use. 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 text on screen information is provided which meets the requirements under IVDR Annex I, 20.4, it should be considered as instructions for use and translated into the required national languages. For all other information, a risk analysis should be performed to determine whether it is considered as necessary for the safe and proper use of the device and should be translated into the required national languages. For example: certain symbols/terms which may be expected to be understood by the user, e.g., 'FILE' or 'HELP' may be left as they are in the text on the screen as long as explanation is provided in the instructions for use.

Where translated text is provided, it can be made available:

- 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.

IVDs intended for self-testing

For IVDs for self-testing, taking into account the type of users, the need to provide full translation of the whole IVD documentation (including the texts displayed on the screens) into the required national language(s), is clearly recognized by all parties. Where the information is not covered by Annex I, Section 20, a risk analysis could be performed to determine whether it is considered as necessary for the safe and proper use of the device and should be translated into the required national languages.

Conclusion

The IVD Industry believes text displayed on the screens does not need to be translated unless it falls under IVDR Annex I, 20.4 which is then considered as instructions for use and should then be provided in the appropriate languages. Translations 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.

About MedTech Europe

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies as well as a network of national medical technology associations who research, develop, manufacture, distribute and supply health-related technologies, services and solutions.

For more information, visit www.medtecheurope.org.

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