

## **Information regarding the Norwegian language requirement on information supplied with medical devices**

### **The main rule**

Information supplied must be in Norwegian.

Unofficial translation of the Norwegian regulation no. 1690 of 2005 § 2-6:

*§ 2-6 Language Information required according to directive 90/385/EEC annex I section 13, 14 and 15, directive 93/42/EEC annex I section 13 and directive 98/79/EC annex I part B section 8 must be in Norwegian. The information may be given by harmonised symbols or recognised codes or other measures. For devices for use in clinical investigations another language than Norwegian may be used if this is accepted by the user. Information that is meant to be given to the patient must be in Norwegian. If safe and correct use is ensured, the Directorate of Health may give an exemption from the language requirement.*

The information that is required in relations to the different annexes as listed in § 2-6 first section must be in Norwegian. It is only the information listed in the different annexes that must be in Norwegian. A manufacturer should read them carefully as not everything listed in the annexes are relevant to all types of devices. The starting points in all annexes are that each device must be accompanied by the information needed to use it safely and properly, taking account of the training and knowledge of the potential user.

This information comprises the details on the label and the data in the instructions for use.

### **Exemption**

It is possible to apply the Norwegian Medicines Agency for an exemption from the main rule. The regulation § 2-6 fourth section reads: *If safe and proper use is ensured, the Norwegian Medicines Agency may give an exemption from the language requirement.*

The exemption rule is interpreted strictly, and the manufacturer will need to present convincing arguments on why the device should not have to follow the main rule. The exemption is used for instance in cases where a device is needed for a specific patient or task and there is no alternative device available nor time for translation.

Send your application to the Norwegian Medicines Agency with the following information:

1. Background for the application
2. Name of the device and a description of usage
3. EC-certificate of the device (where appropriate) and the Declaration of Conformity
4. Name of the user of the device (example. health institution, hospital).
5. Statement from the user on safe and proper use without Norwegian manual/label.
6. A copy of the instructions for use /the label

The Norwegian Medicines Agency will take into consideration:

1. the training and knowledge of the user
2. if the user of the device is a professional or a lay person and
3. if there are other corresponding devices on the market that fulfil the requirements.

### **Standards**

An interpretation on the different requirements in the annexes are presented in standards (the list is not exhaustive).

Directive 90/385/EEC and Directive 93/42/EEC:

- EN 1041:1998 Information supplied by the manufacturer with medical device

Directive 98/79/EC

- EN 375:2001 Information supplied by the manufacturer with in vitro diagnostic reagents for professional use.
- EN 376:2002 Information supplied by the manufacturer with in vitro diagnostic reagents for self-testing
- EN 591:2001 Instructions for use for in vitro diagnostic instruments for professional use -  
EN 592:2002 Instructions for use for in vitro diagnostic instruments for self-testing All directives:
- EN 980:2003 Graphical symbols for use in the labelling of medical devices

A manufacturer is encouraged to use these standards. Where appropriate, this information should take the form of symbols. Any symbol or identification colour used must conform to the harmonized standards. The examples listed in the rest of this information are intended as a general guidance and should not be regarded as an authoritative statement of the law, nor as having any legal consequence

### **Service manual**

Service manuals are not comprised by the annexes and it is therefore not required to translate them into Norwegian.

### **Technical documentation and declaration of conformity**

Technical documentation is not comprised by the annexes, and it is therefore not required to translate them into Norwegian. With regard to the Norwegian regulation § 6-2 the declaration of conformity must be in Norwegian or English.

### **Software**

The Norwegian language requirement also applies to software that is covered by the relevant annexes of the medical devices directives.

### **Electronic instructions for use**

Instructions for use of medical devices may be provided in electronic form instead of in paper form. Information in the electronic instructions for use shall be in Norwegian.

Instructions for use in electronic form means:

1. instructions for use displayed in electronic form by the device,
2. contained in portable electronic storage media supplied by the manufacturer together with the device, or
3. instructions for use available through a website;

Last update:15.04.2018