## LANGUAGE REQUIREMENTS FOR MEDICAL DEVICES IN FINLAND

Referring to your request on the language requirements for medical devices in Finland we would like to give you the following response.

The Chapter 3 paragraph 12 of the Medical Devices Act 629/2010 contains the labelling requirements in Finland: ”Information accompanying the device must be in Finnish, Swedish or English, unless the information takes the form of generally known direction or warning symbols. Information intended for users or patients to ensure the safe use of the device must be in Finnish and Swedish. Based on the risk analysis the manufacturer has to specify the information needed to ensure the safe use. The instructions for use and labelling of medical devices intended for selftesting must be in Finnish and Swedish.”

The wording of the paragraph is intended to give flexibility for the manufacturer but also to safeguard the user and the patient. The need to use the language of the user depends on the device itself and its intended purpose specified by the manufacturer. The envisaged education and skills of the user are also important criteria.

The manufacturer should address the language issue during the risk analysis that is mandatory for each device. Depending on the results of the risk analysis the manufacturer makes the decisions concerning the labelling. When the device is placed on the market with a CE marking the manufacturer shall continuously monitor the adequacy of the labelling and instructions for use to avoid incidents that could lead to the death or serious deterioration in the state of health of a patient, user or other person. The Chapter 3 paragraph 12 of the Medical Devices Act 629/2010 accepts also English to be used in the labelling. It is the manufacturer’s obligation to identify the risks that are related to the language of the labelling. This fact cannot be overruled by exemptions.

We hope that this response helps you in your decision-making.