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LANGUAGE REQUIREMENTS FOR MEDICAL DEVICES IN FINLAND

The Section 5 paragraph 1 of the Medical Devices Act 719/2021 contains the languague requirements in Finland: ”The information and documents referred to in Article 10(11) of the MD Regulation and in Article 10(10) of the IVD Regulation must be in Finnish, Swedish or English, unless the information is provided in the form of internationally recognised symbols. Information necessary for the safe use of a device must, however, be available in Finnish and in Swedish. The manufacturer must determine, based on a risk assessment, which information is necessary for safe use. If a device is intended for use by patients or other consumers, instructions for use and other information necessary for safe labels of single use must be available in Finnish and in Swedish. The instructions for use and use devices referred to in the MD Regulation must be either in Finnish or in Swedish or in both languages, depending on the user’s needs.” (see more requirements in the section 5 paragraphs 2 to 5, which references to the MDR/IVDR regulations).

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 Section 5 paragraph 1 of the Medical Devices Act 719/2021 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.

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