EU MEDICAL and IVD DEVICE LABELING:

TRANSLATION REQUIREMENTS and TRENDS

As of January 1, 2007, the European Union (EU) consists of 27 countries, close to 500 million consumers who communicate in 22 different languages. These countries have adopted into their National Law the three EU Medical Directives: 1) Active Implantable Medical Devices (AIMD), 2) Medical Devices (MDD), 3) In- Vitro Diagnostic Devices (IVD).

While adopting the directives into National Law, all EU countries, referred to as Member States, are given the right to add National language requirements to be shown on the medical device labels and instructions for use for when the device reaches the final user, regardless of whether it is for professional use or other use. The majority of the Member States have opted for their own National language(s), which is published in their National Law not the Directives. In a few cases countries opted for another community language.

There is no trend towards elimination of translations. However, there is a trend towards simplification in order to minimize the cost of translation efforts including a strong recommendation to use the symbols published in harmonized standards instead of text.

During 2007 a guideline for In-Vitro Diagnostic Devices only, covering labels, instructions for use (IFU) and other information was published. This guideline outlines non-paper alternatives, including electronic labeling and instructions for use, for Professional Use. In-Vitro Diagnostic Devices for laypersons still require paper format labels and IFU's. This guideline provides specifics that every IVD manufacturer needs to be aware of.

As of late 2007, decisions on electronic labeling to be allowed under the Medical Device and Implantable Devices Directives continue to be open issues awaiting a decision.

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For your immediate use, we submit a list of languages as adopted into National Law by each EU State. This list is subject to change without notice.

EU Countries in Blue EFTA Countries in Red	Instructions For Use (IFU)+ Label Language Requirements	National requirements in Addition to directives
AUSTRIA	German	None
BELGIUM	Dutch + German + French (All three must be used for patient instructions)	None
BULGARIA	Bulgarian English labels for professional use only.	Software may be in English.
CROATIA (Pending EU State)	Croatian	Old regulations
CYPRUS	Non-professional use devices in Greek. Professional Use devices in Greek or English	Packaging must show: Sterile devices LOT Custom made devices – MDD Custom made devices – AIMD Devices intended for performance evaluation IN GREEK CHARACTERS Amendment to accept English for these exceptions is pending.
CZECH REPUBLIC	Czech	None
DENMARK	Danish	None
ESTONIA	Estonian	IVDD Regulation 54/1999 for *professional* users: Labels and accompanying documentation must be in Estonian. IVDD Regulation 41/2000 for *manufacturers and suppliers:* Only information necessary for safe use of the device must be provided in Estonian.

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		MDD: Estonian Only
FINLAND	Finnish + Swedish	None
FRANCE	French	May want to check technical documentation/clinical trial information in French.
GERMANY	German	None
GREECE	Greek	None
HUNGARY	MDD + AIMD: Hungarian IVDD Instructions For Use MUST be in Hungarian	
ICELAND	Icelandic	None
IRELAND	English	None
ITALY	Italian	None
LATVIA	Latvian- For professional use English or German is accepted (MDD and IVDD)	
LIECHTENSTEIN	German	None
LITHUANIA	Lithuanian All product labels + Instructions For Use	None
LUXEMBOURG	French	None
MACEDONIA (Pending EU State)		
MALTA	Maltese or English	IVDD: Label + IFU can be provided in Maltese or English.
NETHERLANDS	Dutch	MDD: Dutch language waiver possible upon special application to Dutch Competent Authorities.

		IVDD: English language possible if accompanied by continuous verification process by manufacturer.
NORWAY	Norwegian	None
POLAND	Polish	IVDD + MDD: For devices used by professionals only and upon user's written consent, IFU can be provided in language other than Polish.
PORTUGAL	Portuguese	None
ROMANIA	Romanian	MDD Labels may be in English. IFU + CE Certificates must be in Romanian by a certified translator.
SERBIA (Pending EU State)	Serbian	
SLOVAKIA	Slovak Some Czech accepted, be sure to clarify first.	
SLOVENIA	Slovenian	Labels and IFU must be in Slovenian. Slovenian IFU for self-testing IVD devices is mandatory. Professional medical staff devices IFU may be in Slovenian or English.
SPAIN	Spanish	Requires submittance of labeling text to Competent Authorities. Accident reports may be filed in English.
SWEDEN	Swedish	None
SWITZERLAND	French, German, Italian	None

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TURKEY (Pending EU State)	Turkish	Has adopted all EU Medical Directives.
UNITED KINGDOM	English	Manufacturers name on label must be more prominent than any other name.

QNET LLC - Prepare labels to meet both EU and FDA requirements. Just ask us!

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