

# **THE NEW EU**

## **29 COUNTRIES**

## **22 LANGUAGES**

## **467 MILLION CONSUMERS**

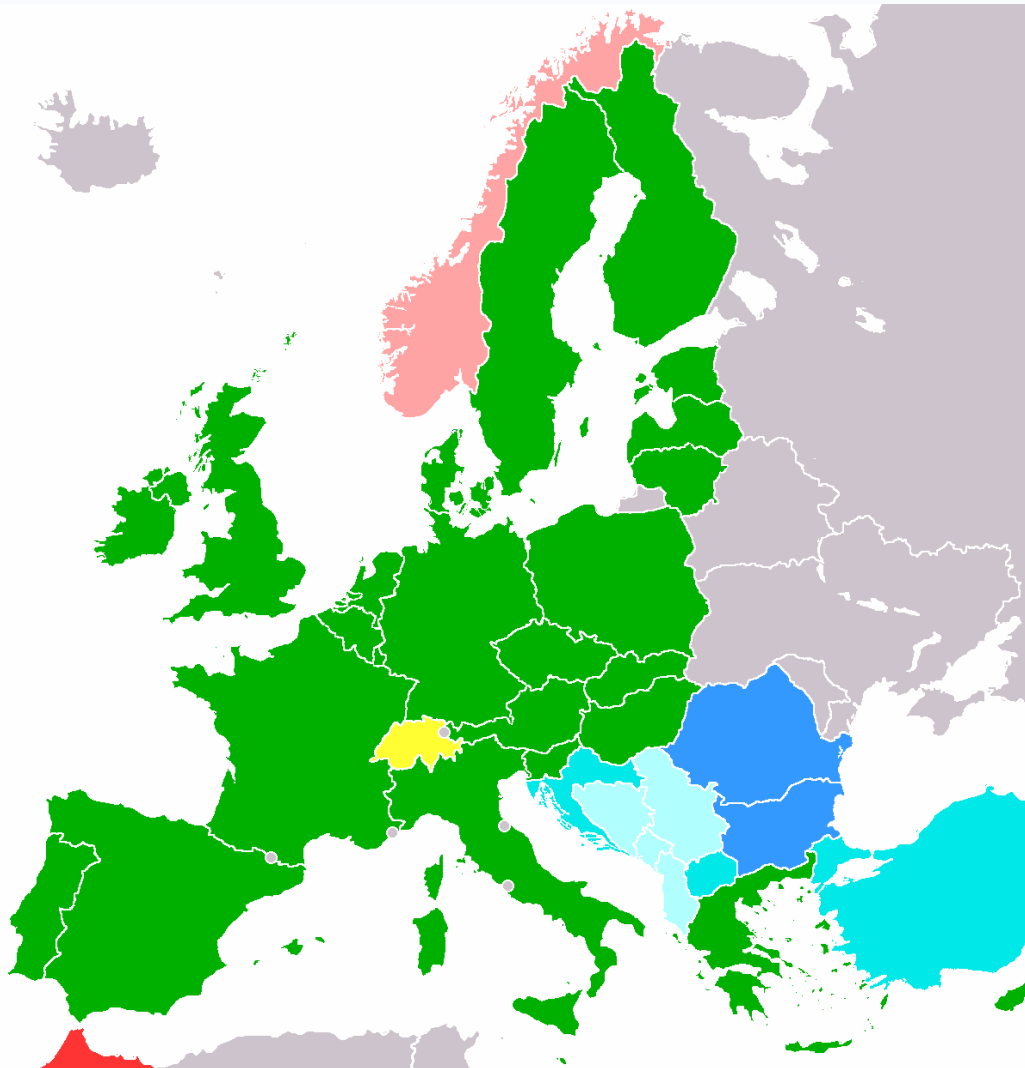
On May 1, 2004 the EU grew by 10 countries. Meanwhile (October 2006) the three EU Medical Directives:

- 1) Active Implantable Medical devices (AIMD);
- 2) Medical Devices (MDD);
- 3) In-Vitro Diagnostic Devices (IVDD)

have been implemented and are effective in these 10 new member states.

In some cases a few transposition issues remain to be resolved. An example is the lack of appointing a National Notified Body. Overall the 10 new EU States show a great deal of compliance in meeting the competitive, legislative and institutional changes set by the European Commission. In practice one might still encounter lack of knowledge and unwillingness to accept CE rules when dealing with customs, importation agencies and administrators.

We continue to monitor progress and changes, also in relation to the acceptance of new candidate member states Romania and Bulgaria; the official decision on their date of joining (probably 1 January 2007). Croatia, the Republic of Macedonia and Turkey are officially candidate countries. Croatia and Turkey are currently in accession negotiations, while the negotiations with the Republic of Macedonia have not yet started. The remaining states in the Balkans are officially “potential candidate countries”, which means they have a clear perspective for accession over the next decades.



- current members
- acceding countries
- candidate countries
- potential candidate countries
- application frozen
- application rejected by EC
- accession rejected in a referendum

(source: [www.wikipedia.org](http://www.wikipedia.org))

However, the most important issue continues to be translations into now 22 languages. It is a real hurdle and manufacturers must weigh the cost of translating labels and instructions for use, while assessing if it is worth entering these new markets. Since eliminating translations is not an option, the attention has turned to cost effective methods of providing translations on a CD-Rom or via Internet. The acceptance of these electronic formats is still under discussion.

For your immediate use, we submit the status of the three medical directives for the present and pending EU States:

EU State	MDD – IVDD- AIMD Directives accepted	'Instructions for use (IFU)' 'Label language' -requirements	National requirements (in addition to Directives)	IFU + Label: CD-ROM / Internet Accept: Y/N	National Notified Body Y/N
<b>Austria</b>	√	- German	None	Yes	Yes
<b>Belgium</b>	√	- Dutch - French - German <i>All three must be used for patient instructions</i>	None	No	Yes
<b>Bulgaria</b> <i>(Pending 2007)</i>		- English - Bulgarian <i>(for self-test devices only)</i>	Old regulations	Unknown	No
<b>Croatia</b> <i>(Pending)</i>		-			
<b>Czech Republic</b>	√	- Czech	No fee, all risk, device registration to the Czech Ministry of Healthcare	No	Yes
<b>Cyprus</b>	√	- Greek <i>(Non-professional use devices)</i> - Greek or English <i>(Professional use devices)</i>	Packaging must show <u>IN GREEK CHARACTERS:</u> - Sterile devices - LOT - Custom made devices-MDD - Custom made devices-AIMD - Devices intended for performance evaluation  <i>Amendment to accept English for these exceptions is pending.</i>	Yes	No
<b>Denmark</b>	√	- Danish	None	Yes	Yes

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<b>Estonia</b>	√	- Estonian	<p><u>IVDD Regulation 54/1999 for professional users:</u></p> <ul style="list-style-type: none"> <li>- Labels and accompanying documentation must be in Estonian.</li> </ul> <p><u>IVDD Regulation 41/2000 for manufacturers and suppliers:</u></p> <ul style="list-style-type: none"> <li>- Only information necessary for safe use of the device must be provided in Estonian.</li> </ul> <p><u>MDD:</u></p> <ul style="list-style-type: none"> <li>- Estonian only</li> </ul>	No	No
<b>Finland</b>	√	- Finnish - Swedish	None	Yes	Yes
<b>France</b>	√	- French	May want to check technical documentation/clinical trial information in French	Yes	Yes
<b>Germany</b>	√	- German	None <i>(Due to 5 regional competent authorities differences in compliance interpretation continue to be problematic)</i>	Reluctant	Yes
<b>Greece</b>	√	- Greek	None	Yes	Yes
<b>Hungary</b>	√	- Hungarian (MDD + AIMD)  <i>IVDD Instructions for use <u>MUST</u> be in Hungarian.</i>	<ul style="list-style-type: none"> <li>- Hungarian manufacturers only must register Risk Class I devices.</li> <li>- Adverse events must be reported within 8 days</li> </ul>	No	Yes

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Iceland	√	- Icelandic	None	No	No
Ireland	√	- English	None	Yes	Yes
Italy	√	- Italian	None	Unknown	Yes
Latvia	√	- Latvian - English or German ( <i>accepted for professional use (MDD and IVDD)</i> )	- Three medical device directives are prepared for approval by cabinet of ministries (probably Oct. 2004). - Latvia accepts current status of the EU, MDD, IVDD and AIMD without exceptions. - Specific questions may be directed to the "health statistics and medical technologies agency, health ministry of Latvia.	No	No
Liechtenstein	√	- German	None	Unknown	No
Lithuania	√	- Lithuanian ( <i>All product labels + instructions for use</i> )	None	No	Yes
Luxembourg	√	- French - German - Luxembourgish	None	Unknown	Yes
Macedonia (pending)					
Malta	√	- Maltese - English	IVDD: Label + IFU can be provided in Maltese or English		No
Montenegro (no time frame set)		-			

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Netherlands	√	- Dutch	None	Reluctant	Yes
Norway	√	- Norwegian	None	Unknown	Yes
Poland	√	- Polish  <u>IVDD + MDD:</u> For devices used by professionals only and upon user's written consent, IFU can be provided <u>in language other than Polish.</u>	- IVDD Annex II + self test devices only: labels + IFU mandatory - AR domiciled in the EU - Polish device manufacturers <u>only</u> must notify CA of <u>all</u> devices being placed on the market - EU + EFTA manufacturer placing on the market AIMD or MDD Class IIb or III, or IVDD List A + B + self testing devices must register these devices - A fee applies to all registrations	Unknown	Yes
Portugal	√	- Portuguese	None	Yes	Yes

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<b>Romania</b> <i>(pending 2007)</i>		<ul style="list-style-type: none"> <li>- Romanian</li> <li>- MDD Labels may be in English</li> <li>- IFU + CE Certificates must be in Romanian by a certified translator</li> <li>- Accident reports may be filed in English</li> </ul>	<ul style="list-style-type: none"> <li>- Mandatory device registration of all risk levels, a fee applies, 30 day process, registration certificate is valid for 5 years</li> <li>- Authorized representative domiciled in Romania</li> <li>- MDD certification issued by Romanian Certification body in Romanian only.</li> <li>- IVDD certification issued by a Notified Body in Romanian.</li> <li>- User manual must be delivered with the device in hard copy.</li> <li>- No re-use of single used devices allowed</li> </ul>	Under future consideration	Yes
<b>Serbia</b> <i>(no time frame set)</i>		<ul style="list-style-type: none"> <li>- Serbian</li> </ul>	<ul style="list-style-type: none"> <li>- IVDD – IFU: In Serbian, translated by court interpreter.</li> <li>- IVDD- Label: Name of manufacturer and name of Yugoslavian agent or importer + registration number given with the sale authorization</li> </ul>	No	No
<b>Slovakia</b>	√	<ul style="list-style-type: none"> <li>- Slovak</li> <li>- Some Czech accepted, <i>be sure to clarify first.</i></li> </ul>	<ul style="list-style-type: none"> <li>- Authorized Representative</li> <li>- Domiciled in Slovakia, changes to EU domiciled AR pending (Sept 2004)</li> </ul>	No	Yes

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<b>Slovenia</b>	√	<ul style="list-style-type: none"> <li>- Slovenian</li> <li>- Labels and IFU must be in Slovenian.</li> <li>- Slovenian instructions for Use for <u>self-testing</u> IVDD devices is mandatory</li> <li>- <u>Professional medical staff devices</u> instructions for use may be in Slovenian or English</li> </ul>	<ul style="list-style-type: none"> <li>- Instructions for use must be inside the packaging.</li> <li>- Local manufacturers, sterilizers, suppliers (wholesale + retail) must be registered with the Agency for medicinal products and medical devices.</li> </ul> Vigilance reporting: <ul style="list-style-type: none"> <li>- 15-30 days for intoxications</li> <li>- 24 hours in case of deaths</li> </ul>	No	Yes
<b>Spain</b>	√	<ul style="list-style-type: none"> <li>- Spanish</li> </ul>	<ul style="list-style-type: none"> <li>- Requires submittance of labeling text to Competent Authorities.</li> <li>- Accident reports may be filed in English</li> <li>- Lot or Serial number must be included for traceability</li> <li>- Additional warning statements for syringes, needles, condoms.</li> </ul>	Unknown	Yes
<b>Sweden</b>	√	<ul style="list-style-type: none"> <li>- Swedish</li> </ul>	None	Unknown	Yes
<b>Switzerland</b>	√	<ul style="list-style-type: none"> <li>- French</li> <li>- German</li> <li>- Italian</li> </ul>	None	Unknown	
<b>Turkey</b> (Pending)	√	<ul style="list-style-type: none"> <li>- Turkish</li> </ul>	Turkish AR on label	Unknown	Yes
<b>UK</b>	√	<ul style="list-style-type: none"> <li>- English</li> </ul>	Manufacturer's name on label must be more prominent than any other name.	Yes	Yes