Form for the registration of manufacturers and devices In Vitro Diagnostic Medical Device Directive, Article 10

(Version January 2007)

	A. Identification of the Competent Authority		
6100	Competent Authority code [1]		
6110	Competent Authority name		
6120	Country code [2]		
6140	City	6150	Postal code
6160	Street, number	6165	PO box
6170	Telephone number	6180	Fax number
6190	E-mail		

	B. Identification of the registration		
6200	Date of registration [3]	6210	Registration number [4]
6220	Indicate if this is a first registration, a change of information, a discontinuation or a withdrawal of a registration: [5]		
	first	change of address	discontinuation by manufacturer
		significant change of product	withdrawal by Competent Authority
6230	If change, discontinuation or withdrawal provide previous registration number		
6240	Status of the organization making this registration application: [6]		
	Manufacturer	Authorized representative	

I affirm that the information given above is correct to the best of my knowledge.

City…… Date……

Name…… Signature……..

City..... Date .....

	C. Identification of the Manufacturer [7]		
6250	Manufacturer code [8]		
6260	Manufacturer name, long		
6265	Manufacturer name, short		
6270	Country code [2]		
6290	City	6300	Postal code
6310	Street, number	6315	PO box
6320	Contact point Name	6330	Telephone number
6340	Fax number	6350	E-mail

	D. Identification of the authorized representative[9]
6370	Representative code [8]
6380	Representative name
6390	Country code [2]

6392	City	6394	Postal code
6396	Street, number	6398	PO box
	Contact point		
6400	Name	6410	Telephone number
6420	Fax number	6430	E-mail

I affirm that the information given above is correct to the best of my knowledge.

City…… Date……

Name…… Signature……..

	E. Identification of the concerned device
6440	Classification of the concerned device [10)]
	Device of List A, Annex II
	Device of List B, Annex II
	Device for self-testing not listed in Annex II
	Other device (all devices except Annex II and self-testing devices)
6445	Notification according article 10(4)
	„New“ product [11)]
6446	Device Category Code [12)]
	06
	Device Category Term [12)]
6447	In local language [13)]
6448	In English
	In vitro diagnostic devices

	E.1 Information related to reagents, reagents products, calibration and control materials: **In terms of common technological characteristics and/or analytes**				
6450	Nomenclature system used [14)]				
	GMDN		EDMS		
6460	Local language [15)]				
6465	Generic Device Group Code		Generic Device Group Term[16)]		
		6470	In local language [13)]	6480	In English

	Short description [17)]		
6490	In local language [13)]	6500	In English

	E.3 Additional information for Annex II and self-testing devices: Identification of the device **(Note: this form does not contain data related to analytical or diagnostic parameters, or the outcome of performance evaluations. Instead this will be available in the instructions for use and held on file by the manufacturer)**		
6605	Device Type [18)]		
6610	Conformity checked by Notified Body	6615	Notified Body identification number
6620	In conformity with Common Technical Specifications (for Annex II List A devices)		

I affirm that the information given above is correct to the best of my knowledge.

City…… Date……

Name…… Signature……..

	E. Identification of the concerned device
6440	Classification of the concerned device [10)] Device of List A, Annex II Device of List B, Annex II Device for self-testing not listed in Annex II Other device (all devices except Annex II and self-testing devices)
6445	Notification according article 10(4) „New“ product [11)]
6446	Device Category Code [12)] ***06***
6447	Device Category Term [12)] In local language [13)]
6448	In English ***In vitro diagnostic devices***

	E.2 Information related to other IVDs: appropriate indications				
6550	Nomenclature system used[14)] GMDN EDMS				
6560	Local language[15)]				
6565	Generic Device Group Code		Generic Device Group Term[16)]		
		6570	In local language	6580	In English
	Short description[17)]				

6590	In local language	6600	In English

	E.3 Additional information for Annex II and self-testing devices: Identification of the device **(Note: this form does not contain data related to analytical or diagnostic parameters, or the outcome of performance evaluations. Instead this will be available in the instructions for use and held on file by the manufacturer)**		
6605	Device Type [18)]		
6610	Conformity checked by Notified Body	6615	Notified Body identification number
6620	In conformity with Common Technical Specifications (for Annex II List A devices)		

I affirm that the information given above is correct to the best of my knowledge.

City…… Date……

Name…… Signature……..

Notes on completing the form for the registration pursuant to article 10 IVD-Medical Device Directive

[1)] Composed of the two-letter country code of ISO 3166 followed by a slash, CA and the number of the Competent Authority in the state, e.g.: ES/CA01.

[2)] Two-letter code of ISO 3166 (1993), e.g.:

AT	Austria	IE	Ireland
AU	Australia	IS	Iceland
BE	Belgium	IT	Italy
BG	Bulgaria	LI	Liechtenstein
CA	Canada	LT	Lithuania
CH	Switzerland	LU	Luxembourg
CY	Cyprus	LV	Latvia
CZ	Czech Republic	MT	Malta
DE	Germany	NL	Netherlands
DK	Denmark	NO	Norway
EE	Estonia	PL	Poland
ES	Spain	PT	Portugal
FI	Finland	RO	Romania
FR	France	SE	Sweden
GB	United Kingdom	SI	Slovenia
GR	Greece	SK	Slovakia
HU	Hungary	TR	Turkey

[3)] YYYY-MM-DD

[4)] To be assigned by the Competent Authority. Composed of the two-letter country code of ISO 3166 followed by a slash, the code of the Competent Authority, a slash and an internal registration number, e.g.: ES/CA01/nnn...

[5)] "Change" must be marked for all types of reported changes. Only one change may be reported per notification of change (e.g. either change of address ***or*** discontinuation / withdrawal of IVD medical device).

☐ change of address: A notification of change concerning the address must contain the relevant manufacturer / authorized representative ***code*** and the complete address block to be changed. No further data should be submitted.

☐ significant change of product: In case a **significant** change of IVD medical device is reported, "change of product" must be marked and the "previous registration number" must be given. The form must be filled in completely (the definition of significant change must be generated)

☐ discontinuation by manufacturer: Discontinuation of placing on the market.

☐ withdrawal by Competent Authority: Withdrawal of devices or group of devices as identified in section E.

[6)] References to the IVD MDD 98/79/EC:
Manufacturer (art. 10(1)); authorized representative (art. 10(3)).

[7)] The address of the manufacturer should be stated and should be the same as the manufacturer's address stated on the label

[8)] Assigned by the manufacturer or the authorized representative. This code is always composed of the two-letter country code of ISO 3166 followed by a slash and a standardized coding system for manufacturers and authorized representatives adopted by a state. Only one system has to be used within a state.

[9)] To be filled in if the manufacturer has nominated an authorized representative.

[10)] Multiple entries are not possible.

For all devices: fill E.1 or E2.

For Annex II and self-testing devices: fill also E.3

[11)] According article 10(4), a device is „new" if:

- there has been no such device continuously available on the Community market during the previous three years for the relevant analyte or other parameter

- the procedure involves analytical technology not continuously used in connection with a given analyte or other parameter on the Community market during the previous three years

[12)] "Device Category ", „Generic Device Group" and „Device Type" are based on prEN ISO 15225

[13)] If available

[14)] Generic Device Group code and term have to be taken from the Global Medical Device Nomenclature (GMDN) when available. If the GMDN is not ready in time, device code and term will have to be taken from the European Diagnostic Market Statistics Nomenclature (EDMS). The EDMS is available on the following WEB site: http://www.edma-ivd.be.

[15)] Two-letter code of ISO 639 (1988), e.g.:

bg	Bulgarian	lt	Lithuanian
cs	Czech	lv	Latvian
da	Danish	mt	Maltese
de	German	nl	Dutch
el	Greek	no	Norwegian
en	English	pl	Polish
es	Spanish	pt	Portugese
et	Estonian	ro	Romanian
fi	Finnish	sk	Slovak
fr	French	sl	Slovenian
hu	Hungarian	sv	Swedish
is	Icelandic	tr	Turkish
it	Italian		

Only one Non-English language is permitted to be used in " device term", "short description" and "device category term" (No. 6470, 6490, 6540).

[16)] If Generic Device Group code and term are taken from the European Diagnostic Market Statistics Nomenclature (EDMS):

IVD Reagents: Level 5 („Method") or if not available Level 4 ("Parameter") has to be used

IVD Instruments: Level 3 ("Subgroup") of the instrument grouping has to be used.

If Generic Device Group code and term are taken from the Global Medical Device Nomenclature (GMDN):

Preferred term has to be used

[17)] Only compulsory, if no right device code/term has been given. Please use appropriate terms or a short phrase. The phrase can include basic features of the product such as, for example, the intended use, the aspects governing its

[18)] Manufacturer product name