# 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 | | |

| | | | |
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| | **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<br>Name | 6330 | Telephone number |
| 6340 | Fax number | 6350 | E-mail |

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

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

| | | | | | |
|---|---|---|---|---|---|
| | **E.2 Information related to other IVDs: appropriate indications** | | | | |
| 6550 | Nomenclature system used[14)]<br>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**<br>**(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