

## Form for the registration of manufacturers and devices In Vitro Diagnostic Medical Device Directive: article 10

<b>A. Identification of the Competent Authority</b>	
6100	Competent Authority code <sup>1)</sup>
6110	Competent Authority name
6120	Country code <sup>2)</sup>
6140	City
6150	Postal code
6160	Street, number
6165	PO box
6170	Telephone number
6180	Fax number
6190	E-mail
<b>B. Identification of the registration</b>	
6200	Date of registration <sup>3)</sup>
6210	Registration number <sup>4)</sup>
6220	Indicate if this is a first registration, a change of information, a discontinuation or a withdrawal of a registration: <sup>5)</sup> <input type="checkbox"/> first <input type="checkbox"/> change of address <input type="checkbox"/> discontinuation by manufacturer <input type="checkbox"/> significant change of product <input type="checkbox"/> withdrawal by Competent Authority
6230	If change, discontinuation or withdrawal provide previous registration number
6240	Status of the organization making this registration application: <sup>6)</sup> <input type="checkbox"/> Manufacturer <input type="checkbox"/> Authorized representative
<b>C. Identification of the Manufacturer <sup>7)</sup></b>	
6250	Manufacturer code <sup>8)</sup>
6260	Manufacturer name, long
6265	Manufacturer name, short
6270	Country code <sup>2)</sup>
6290	City
6300	Postal code
6310	Street, number
6315	PO box
Contact point	
6320	Name
6330	Telephone number
6340	Fax number
6350	E-mail

<b>D. Identification of the authorized representative<sup>9)</sup></b>			
6370	Representative code <sup>8)</sup>		
6380	Representative name		
6390	Country code <sup>2)</sup>		
6392	City	6394	Postal code
6396	Street, number	6398	PO box
Contact point			
6400	Name	6410	Telephone number
6420	Fax number	6430	E-mail
<b>E. Identification of the concerned device</b>			
6440	Classification of the concerned device <sup>10)</sup>		
	<input type="checkbox"/> Device of List A, Annex II		
	<input type="checkbox"/> Device of List B, Annex II		
	<input type="checkbox"/> Device for self-testing not listed in Annex II		
	<input type="checkbox"/> Other device (all devices except Annex II and self-testing devices)		
6445	Notification according article 10(4)		
	<input type="checkbox"/> „New“ product <sup>11)</sup>		
6446	Device Category Code <sup>12)</sup>		
	06		
6447	Device Category Term <sup>12)</sup> In local language <sup>13)</sup>		
6448	In English		
	<i>In vitro diagnostic devices</i>		
<b>E.1 Information related to reagents, reagents products, calibration and control materials: In terms of common technological characteristics and/or analytes</b>			
6450	Nomenclature system used <sup>14)</sup>		
	<input type="checkbox"/> GMDN <span style="margin-left: 200px;"><input type="checkbox"/> EDMS</span>		
6460	Local language <sup>15)</sup>	6465	Generic Device Group Code
6470	Generic Device Group Term <sup>16)</sup> In local language <sup>13)</sup>		
6480	In English		
6490	Short description <sup>17)</sup> In local language <sup>13)</sup>		

6500	In English
<b>E.2 Information related to other IVDs: appropriate indications</b>	
6550	Nomenclature system used <sup>14)</sup> <input type="checkbox"/> GMDN <input type="checkbox"/> EDMS
6560	Local language <sup>15)</sup>
6465	Generic Device Group code
6570	Generic Device Group term <sup>16)</sup> In local language <sup>13)</sup>
6580	In English
6590	Short description <sup>17)</sup> In local language <sup>13)</sup>
6600	In English
<b>E.3 Additional information for Annex II and self-testing devices: Identification of the device</b> <b>(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)</b>	
6605	Device Type <sup>18)</sup>
6610	<input type="checkbox"/> Conformity checked by Notified Body
6615	Notified Body identification number
6620	<input type="checkbox"/> 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	GR	...Greece
AU	...Australia	IE	...Ireland
BE	...Belgium	IS	...Iceland
CA	...Canada	IT	...Italy
CH	...Switzerland	LI	...Liechtenstein
DE	...Germany	LU	...Luxembourg
DK	...Denmark	NL	...Netherlands
ES	...Spain	NO	...Norway
FI	...Finland	PT	...Portugal
FR	...France	SE	...Sweden
GB	...United Kingdom	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.:

da	...Danish	is	...Icelandic
de	...German	it	...Italian
el	...Greek	nl	...Dutch
es	...Spanish	no	...Norwegian
en	...English	pt	...Portuguese
fi	...Finnish	sv	...Swedish
fr	...French	tr	...Turkish

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

<sup>16)</sup> 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

<sup>17)</sup> 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

<sup>18)</sup> Manufacturer product name