

# Declaration Form

natural or legal persons engaged in the manufacture, marketing, distribution, import or export of in vitro diagnostic medical devices

(articles L.5221-3, L.5221-5, R.5221-34 to R.5221-37 of the public health code)

# [ ]  Initial declaration

# [ ]  Amending Declaration (report only what is changed from the original declaration)

# [ ]  Declaration of partial or total cessation of activity

# [ ]  Number of pages of the declaration :

#

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| 1- Identification of the registrant :* Corporate name of the entity or name and surname for natural persons : …………………………………………………………………………………………………………………
* Legal form: .………………………………………………………………………………………
* Head office address: .………………………………………………………………………………..

 ………………………………………………………………………………………………………………….* Name and capacity of the person engaging the liability of the reporting entity: ……………………………………………………………………………. ……………………………………
* Name and position of the person responsible for the declaration: ………………………………………….
	+ Phone number: .……………………………………………………………………………
	+ Fax number : ………………………………………………………………………………
	+ E-mail address : ………………………………………………………………………………
* Number of establishments or sites of the entity including the head office ………………………
* Total number of employees : ………………………………………………………………………………

NB: the agents will indicate in Part 6, the name and head office address of the manufacturer(s) represented by product(s) |

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| 2- Identification of the declarant's status (multiple answers possible) :

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| --- | --- | --- | --- | --- | --- | --- |
| **Manufacturer** | **Agent** | **Importer** | **Exporter** | **Distributor** | **Person****engaged in manufacturing** | **Devices concerned** |
| **[ ]**  | **[ ]**  | **[ ]**  | **[ ]**  | **[ ]**  | **[ ]**  | List A devices  |
| **[ ]**  | **[ ]**  | **[ ]**  | **[ ]**  | **[ ]**  | **[ ]**  | List B devices |
| **[ ]**  | **[ ]**  | **[ ]**  | **[ ]**  | **[ ]**  | **[ ]**  | Self-tests out of lists A and B |
| **[ ]**  | **[ ]**  | **[ ]**  | **[ ]**  | **[ ]**  | **[ ]**  | Other devices |
| **[ ]**  | **[ ]**  | **[ ]**  | **[ ]**  | **[ ]**  | **[ ]**  | Software |
| **[ ]**  | **[ ]**  | **[ ]**  | **[ ]**  | **[ ]**  | **[ ]**  | Accessories  |

NB 1: see definitions of manufacturer, agent, importer, exporter, distributor and accessory in articles R.5221-4 and R.5221-5 of the CSP.NB 2: for persons engaged in manufacturing without placing on the market, complete only parts 2, 3 and 6. |

3- Identification of the entity's establishments :

Fill in as many forms as necessary by recalling the name of the entity: ………………………………….

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| * Establishment n°: …………………………………………………………………………….…………
* Address : .………………………………………………………………………………………………

 ……………………………………………………………………………………………………………….* Name and position of the person in charge of the establishment, if applicable: ……………………………………………………………………………. ………………………………....
	+ Phone number: ……………………………………………………………………….
	+ Fax number:………………………………………………………………………… .
	+ E-mail address: ……………………………………………………………………….
* Number of staff in the establishment…………………………………………………………… .
* Activities carried out within the establishment :

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| --- | --- | --- | --- | --- |
| **Production activities** | **Activities****import** | **Export activities** | **Distribution activities** | Devices concerned |
| **[ ]**  | **[ ]**  | **[ ]**  | **[ ]**  | List A devices |
| **[ ]**  | **[ ]**  | **[ ]**  | **[ ]**  | List B devices |
| **[ ]**  | **[ ]**  | **[ ]**  | **[ ]**  | Self-tests out of lists A and B |
| **[ ]**  | **[ ]**  | **[ ]**  | **[ ]**  | Other devices |
| **[ ]**  | **[ ]**  | **[ ]**  | **[ ]**  | Software |
| **[ ]**  | **[ ]**  | **[ ]**  | **[ ]**  | Accessories |

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| * Establishment n°: …………………………………………………………………………….…………
* Address : .………………………………………………………………………………………………

 ……………………………………………………………………………………………………………….* Name and position of the person in charge of the establishment, if applicable: ……………………………………………………………………………. ………………………………....
	+ Phone number: ……………………………………………………………………….
	+ Fax number:………………………………………………………………………… .
	+ E-mail address: ……………………………………………………………………….
* Number of staff in the establishment…………………………………………………………… .
* Activities carried out within the establishment :

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Production activities** | **Activities****import** | **Export activities** | **Distribution activities** | Devices concerned |
| **[ ]**  | **[ ]**  | **[ ]**  | **[ ]**  | List A devices |
| **[ ]**  | **[ ]**  | **[ ]**  | **[ ]**  | List B devices |
| **[ ]**  | **[ ]**  | **[ ]**  | **[ ]**  | Self-tests out of lists A and B |
| **[ ]**  | **[ ]**  | **[ ]**  | **[ ]**  | Other devices |
| **[ ]**  | **[ ]**  | **[ ]**  | **[ ]**  | Software |
| **[ ]**  | **[ ]**  | **[ ]**  | **[ ]**  | Accessories |

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4- Device identification :

Part 4 is to be completed only by manufacturers and agents; fill in as many forms as necessary by recalling the name of the entity:…………………………………………………………………………… .

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|  |  |  | to be completed only for List A and B devices and non-List A and B self-tests |
| Device (1) | class (2) | GMDN code(3) | conformity assessment procedures  (4) | Organization numbernotified | Certificate No.compliance(5) | date of issueof the certificate |
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1. trade name; indicate here if it is a new device within the meaning of 5° of article R.5221-4 of the CSP
2. devices in list A: indicate A; device in list B: indicate B; self-test out of list A and list B: indicate C; other device: indicate D; software: indicate E; accessory: indicate F
3. in case there is no GMDN code for a device, designate the device in part (1), in addition to the trade name, using the appropriate terms or a short sentence which may include the main characteristics of the device such as, for example, its discipline, its analytical classification, its principle ...
4. indicate the conformity assessment procedures used, making reference to the numbers of the Annexes to Directive 98/79/EC.
5. an amending declaration is necessary in case of modification of the certificate (certificate modified, completed, suspended, withdrawn...)

Recall here the name of the entity……………………………………………………………………………………….

5- Identification of the person in charge of reactovigilance :

Part 5 is to be completed only by manufacturers and agents (article R.5222-11 of the CSP)

* Name and surname: .…………………………………………………………………………………………………
* Quality : …………………………………………………………………………………………………………….
* Mailing address: ………………………………………………………………………………………………….
* E-mail address : .…………………………………………………………………………………………..
* Phone number : ……………………………………………………………………………………………
* Fax number: …………………………………………………………………………………………….

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| 6- Commentary (free text) : |

Date of declaration :

Declarant (name, first name, quality, signature, stamp) :