|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Application for Compassionate Use of a non-CE Marked Medical Device / IVD.** | | | | | | | | |
|  | | | | | | | | |
| **Type of application :** | | | | | | | | |
|  | | | | | | | | |
| **Part 1 – to be filled in by the manufacturer** | | | | | | | | |
|  | | | | | | | | | |
| **Manufacturer** | | | | | | | | |
| Name : | | |  | | | | | |
| Address : | | |  | | | | | |
| Information regarding the contact person for the manufacturer | | | | | | | | |
| First and last name : | | |  | | | | | |
| Phone number : | | |  | | | | | |
| e-mail : | | |  | | | | | |
| **Distributor** | | | | | | | | |
| Name : | | |  | | | | | |
| Address : | | |  | | | | | |
| Information regarding the contact person for the distributor | | | | | | | | |
| First and last name : | | |  | | | | | |
| Phone number : | | |  | | | | | |
| e-mail : | | |  | | | | | |
| **Information regarding the device** | | | | | | | | |
| Trade name : | | |  | | | | | |
| Model : | | |  | | | | | |
| Serial number : | | |  | | | | | |
| Description of the device : | | |  | | | | | |
| If the device is a companion diagnostic, provide information on the accompanying therapy. | | |  | | | | | |
| **Similarity with available devices** | | | | | | | | |
| Are there similar CE-marked devices ? | | | | | | | |  |
| If so, why can’t they be used ? | | | |  | | | | |
| If not, what are the differences with devices / drugs traditionally used for the same medical conditions ? | | | |  | | | | |
| Please also provide information on benefit / risk analysis, risk identification, risk estimation and how these risks have been addressed, as well as information supporting a benefit analysis. | | | | | | | | |
| **Information regarding FDA approval for the device** | | | | | | | | |
| Has the device been approved by the FDA? | | | | | | | |  |
| If so | | Please provide the documents regarding this approval. | | | | | | |
| What is the complete scope ? | | | |  | | |
| **Information regarding clinical investigations / performance evaluations for the device** | | | | | | | | |
| Is the device undergoing clinical investigation / performance evaluation? | | | | |  | | | |
|
| If so (ongoing or finished) | Please provide the documents regarding this investigation. | | | | | | | |
| What is the study title ? | | | | |  | | |
| What is the complete scope ? | | | | |  | | |
| If the clinical investigation is still ongoing, is it located in Belgium ? | | | | | | | |  |
|
| If so, why can’t the patient / patient sample be included in the study ? | | | |  | | | | |
| Signature  Name | | | | | | | **Date :** | |

**Part 2 – to be filled in by a physician – can be find on the next page.**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Application for Compassionate Use of a non-CE Marked Medical Device / IVD.** | | | | | | | |
| **Part 2 to be filled in by a physician** | | | | | | | |
| **physician** | | | | | | | |
| First and last name : |  | | | | | | |
| Phone number : |  | | | | | | |
| e-mail : |  | | | | | | |
| Name of the hospital : |  | | | | | | |
| Address of the hospital : |  | | | | | | |
| Service of the hospital : |  | | | | | | |
| **Patient** | | | | | | | |
| Initials: |  | | | Sex : |  | | |
| Birth date : |  | | | | | | |
| Has the patient been notified that the device is not placed on the market / put into service in accordance with the European legislation? | | | | | | |  |
| If not, what are the reason ? | | | | | | |  |
| Signature of the patient or legally designated representative : | | |  | | | | |
| If legally designated representative, what is the link with the patient? | | |  | | | | |
| Information on the medical conditions of the patient : | |  | | | | | |
| Medical reasons justifying the application : | |  | | | | | |
| Consequences to patient’s condition if the device is not used: | |  | | | | | |
| Is a surgical intervention planned? | | | | | | |  |
| If so, which date ? | |  | | | | | |
| I, the undersigned, ......................................................, take full responsibility for the use of the device requested and will make a complete follow-up of the patient and notify all incidents and / or side effects related to the use of the device. | | | | | | | |
| Signature  Name : | | | | | | **Date :** | |