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| **Application for Compassionate Use of a non-CE Marked Medical Device / IVD.** |
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| **Type of application :** |
|  |
| **Part 1 – to be filled in by the manufacturer** |
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| **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 ? |  |
| SignatureName | **Date :** |

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

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| **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. |
| SignatureName : | **Date :** |